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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	60

Application Number	08/208,972 (Patent No. 5,451,233)
Filing Date	03/09/1994
First Named Inventor	Paul G. Yock
Art Unit	
Examiner Name	N/A
Attorney Docket Number	077843.0113

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ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
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  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
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- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [✓] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
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- [ ] CD, Number of CD(s) _____
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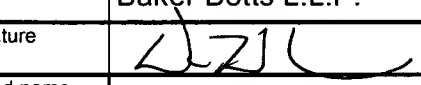
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):

Application for Patent Term Extension Pursuant to 35 U.S.C. Section 156 and Exhibits A-F (see Remarks below).

Remarks

Application for Patent Term Extension (17 pages)
Exhibit A - Acknowledgment and Agreement (2 pages)
Exhibit B - U.S. Patent No. 5,451,233 (12 pages)
Exhibit C - Maintenance Fee History (2 pages)
Exhibit D - Terminal Disclaimer (2 pages)
(see next page)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Baker Botts L.L.P.		
Signature			
Printed name	Daniel J. Hulseberg		
Date	07/25/2008	Reg. No.	36,554

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	N/A		
Typed or printed name	Daniel J. Hulseberg	Date	07/25/2008

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- [✓] Other Enclosure(s) (please Identify below):

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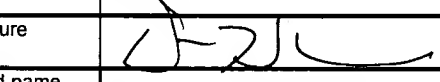
Remarks

Exhibit E - Selected Portions of XIENCE V IFU (17 pages)
Exhibit F - FDA Regulatory Timeline (4 pages)
Power of Attorney (1 page)
Fee Transmittal (1 page)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Baker Botts L.L.P.		
Signature			
Printed name	Daniel J. Hulseberg		
Date	07/25/2008	Reg. No.	36,554

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FEE TRANSMITTAL for FY 2007

Complete if Known	
Application Number	08/208,972 (Patent No. 5,451,233)
Filing Date	03/09/1994
First Named Inventor	Paul G. Yock
Examiner Name	N/A
Art Unit	
Attorney Docket No.	077843.0113

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1,120

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 02-4377

Deposit Account Name: Baker Botts L.L.P.

The Director is authorized to: *(check all that apply)*

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

Extra Claim Fees

	Extra Claims	Fee	Fee Paid
Total Claims		x 50 =	$0
Independent Claims		x 210 =	$0
Multiple Dependent		=	$0
	SUBTOTAL		$0

Fee Description	Large Entity	Small Entity
Claims in excess of 20	50	25
Independent claims in excess of 3	210	105
Multiple dependent claim, if not paid	370	185

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ADDITIONAL FEES

☐ Surcharge - late oath or filing fee	
☐ Non-English Specification	
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☐ Utility Issue Fee	
☐ Design Issue Fee	
☐ Publication Fee	
☐ Petitions to the Commissioner	
☐ Request for Continued Examination (RCE)	
☐ Information Disclosure Statement (IDS)	
Other fee - PTE (37 CFR 1.17(j)(1))	+ $1,120
SUBTOTAL	($) 1,120

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Daniel J. Hulseberg	*Registration No. (Attorney/Agent)*	36,554	*Telephone*	212-408-2500
Signature				*Date*	07/25/2008

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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Application Number	08/208,972(5,451,233)
Filing Date	March 9, 1994
First Named Inventor	Paul G. Yock
Title	Angioplasty Apparatus . .
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	077843.0113

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 62,614

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

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☒ The address associated with the above-mentioned Customer Number.

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OR

☐	Firm or Individual Name				
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature		Date	7/24/08
Name	Paul G. Yock	Telephone	
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: : U.S. Patent No. 5,451,233

Issued: : September 19, 1995 Regulatory Approval Product: XIENCE™ V EECSS

Inventors : Paul G. Yock

For : Angioplasty Apparatus Facilitating Rapid Exchanges

APPLICATION FOR PATENT TERM EXTENSION
PURSUANT TO 35 U.S.C. § 156

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Sir:

This is an application pursuant to 35 U.S.C. § 156 and 37 C.F.R. §1.740 et al. to extend the term of U.S. Patent No. 5,451,233 ("the '233 Patent"), invented and owned by Dr. Paul G. Yock and exclusively licensed to Abbott Cardiovascular Systems Inc. (ACS). ACS, a division of Abbott Laboratories, having a principal place of business of 3200 Lakeside Drive, Santa Clara, California 95054, represents that it is authorized to act as an agent and on behalf of Paul G. Yock in filing the instant Patent Term Extension application as evident from the Acknowledgment and Agreement executed by Dr. Paul G. Yock; a copy of which is attached as Exhibit A.

ACS, acting through its duly authorized attorney, hereby submits this application for extension of patent term under 35 U.S.C. §156 by providing the following information required by the rules promulgated by the PTO (37 CFR. §1.710 - 1.785).

1. A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics; (37 CFR 1.740(a)(1))

The approved product has the trade names "XIENCE™ V Rapid Exchange (RX) Everolimus Eluting Coronary Stent System" and "XIENCE™ V Over-the-Wire (OTW) Everolimus Eluting Coronary Stent System" and will be referred to herein as the "XIENCE V Everolimus Eluting Coronary Stent System" or "XIENCE V EECSS." The approved product has the generic name "Drug Eluting Coronary Stent System (NIQ)."

The XIENCE V EECSS was approved as a medical device indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length $\leq$ 28 mm) with reference vessel diameter of 2.5 mm to 4.0 mm. The approved product generally consists of a Cobalt Chromium (CoCr) alloy metal stent coated with non-erodible polymer and everolimus, and a stent delivery system having either a Rapid Exchange (RX) or an Over-the-Wire (OTW) delivery configuration.

2. A complete identification of the Federal Statute including the applicable provision of law under which the regulatory review occurred; (37 CFR 1.740(a)(2))

The approved device, the XIENCE V EECSS, was subject to regulatory review under Section 515 (21 U.S.C. § 360(e)) and Section 520 (21 U.S.C. § 360(j)) of the Federal Food, Drug and Cosmetics Act as a medical device.

3. An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred; (37 CFR 1.740(a)(3))

The approved medical device, the XIENCE V EECSS, received permission for commercial marketing or use under Section 515 of the Federal Food, Drug and Cosmetics Act on **July 2, 2008**.

4. In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved. (37 CFR 1.740(a)(4))

For the sake of clarity, applicant notes that XIENCE V EECSS is a combination product that includes an everolimus-coated stent and a stent delivery system (SDS). The product was evaluated and approved as a medical device under Section 515 of the Federal Food, Drug and Cosmetics Act. Accordingly, information referenced by 37 CFR 1.740(a)(4) -- which specifies "the case of a drug product" -- is not believed to be required or appropriate for the request for patent term extension based upon the XIENCE V EECSS medical device.

5. A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § l.720(f) and an identification of the date of the last day on which the application could be submitted; (37 CFR 1.740(a)(5))

This application is being submitted within the sixty-day period permitted for submission pursuant to 37 CFR. §1.720(f). In light of the approval date of July 2, 2008, the last day on which this application could be submitted is **August 31, 2008**.

6. A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration; (37 CFR 1.740(a)(6))

The patent for which an extension is being sought is U.S. Patent No. 5,451,233, which issued on September 19, 1995. The inventor is Paul G. Yock. Absent any extension under 35 U.S.C. § 156, U.S. Patent No. 5,451,233 is set to expire on **October 29, 2008**.

7. A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings; (37 CFR 1.740(a)(7))

A copy of U.S. Patent No. 5,451,233, including the entire specification, claims, and drawings is submitted herewith as Exhibit B.

8. A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent; (37 CFR 1.740(a)(8))

Copies of the applicable maintenance fee payment receipts are attached hereto as Exhibit C. A copy of a terminal disclaimer filed in connection with U.S. Patent No. 5,451,233 is attached as Exhibit D. No certificate of correction or reexamination certificate has been obtained in connection with U.S. Patent No. 5,451,233.

9. A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:
(i) The approved product, if the listed claims include any claim to the approved product;
(ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and
(iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product; (37 CFR 1.740(a)(9))

At least claim 3 of the '233 Patent reads on the Rapid Exchange (RX) models of the approved product, which is depicted below (hereinafter, "XIENCE V RX EECSS"). For purpose of reference, Figures 1 and 3A of the '233 Patent are reproduced below as Figures 1 and 2. Figures 3 through 5 below are schematic representations of the XIENCE V RX EECSS, reproduced from PreMarket Approval Application No. P070015; wherein Figure 3 shows the entire length of the device, Figure 4 provides a more detailed view that includes the proximal guidewire opening of the device, and Figure 5 provides a more detailed view that includes the distal guidewire opening of the device. Additionally, relevant sections pertaining to the

configuration and use of the Rapid Exchange (RX) embodiment from the "Instructions For Use" ("IFU") of the approved product are attached as Exhibit E for purpose of reference.

Figure 1 (Figure 1 from the '233 Patent)

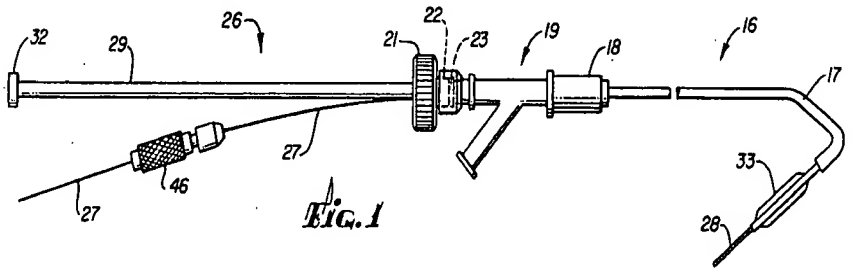

FIG. 1

Figure 2 (Figure 3A from the '233 Patent)

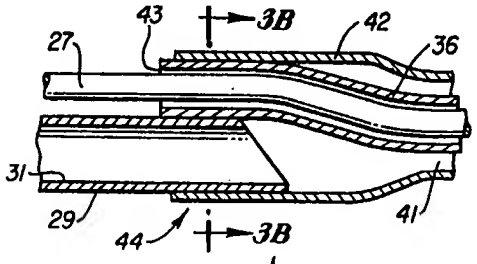

FIG. 3A

Figure 3 (Representation of XIENCE V RX EECSS)

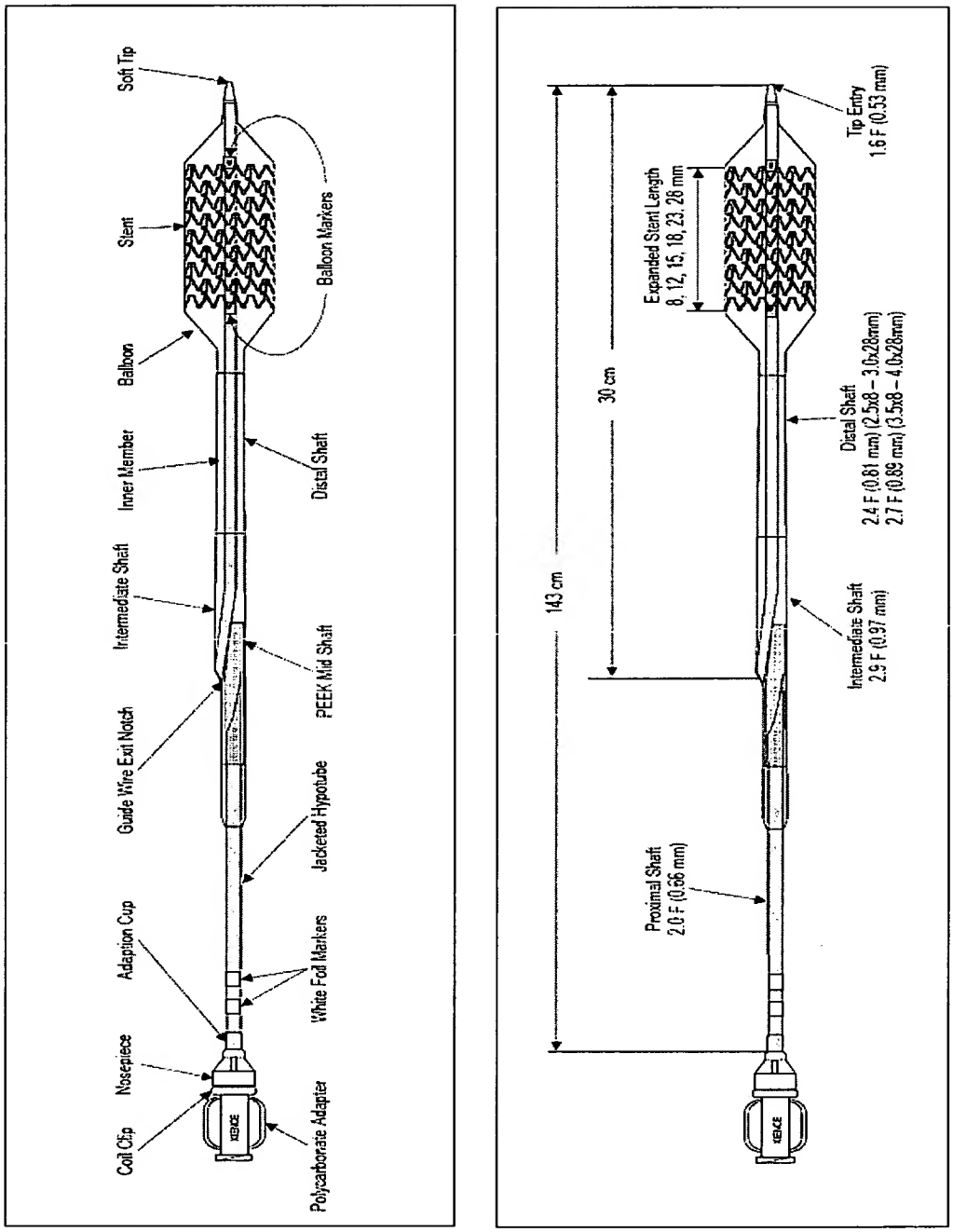

Figure 4 (Detailed Representation of a Portion of the XIENCE V RX EECSS, Including the Proximal Guidewire Opening)

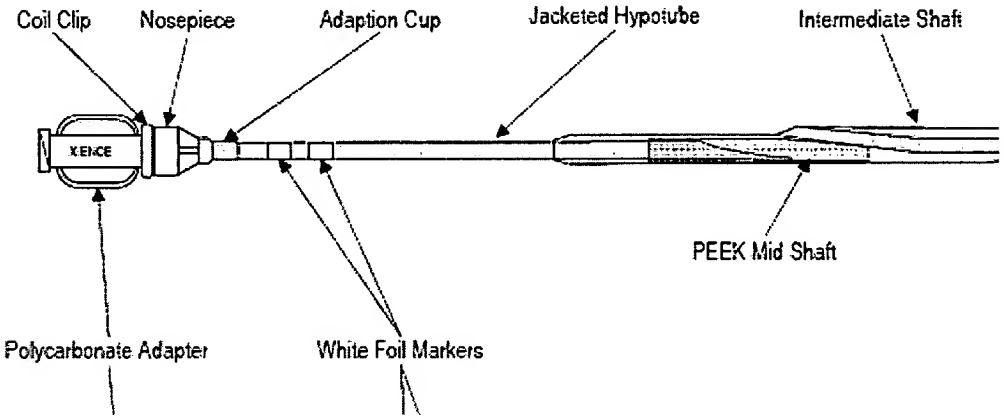

Figure 5 (Detailed Representation of a Portion of the XIENCE V RX EECSS, Including the Distal Guidewire Opening)

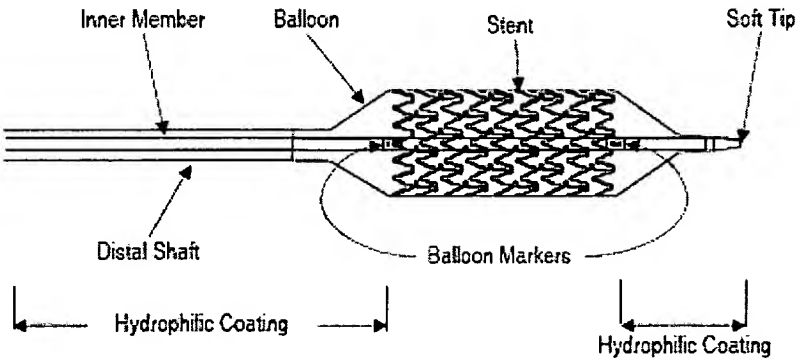

Table 1: Claim Chart Comparing Claim 3 of the '233 Patent to the XIENCE V RX EECSS

Limitation From Claim 3 of U.S. Patent No. 5,451,233 ("233 Patent")	Corresponding Feature in the XIENCE V RX EECSS
3. An elongated balloon dilatation catheter for performing an angioplasty procedure within a human patient's coronary artery which has means for the rapid exchange of the catheter over the guidewire without the utilization of an exchange wire or an extension wire, comprising:	As shown in Figure 3 above, the XIENCE V RX EECSS comprises an elongated catheter with an inflatable balloon. As described in the attached IFU (see Exhibit E), the approved use for the XIENCE V RX EECSS is improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions. Upon inflation of the balloon within a coronary artery, the coronary luminal diameter is generally improved. Such a procedure is recognized as an angioplasty procedure. Thus the XIENCE V RX EECSS comprises an elongated balloon dilatation catheter for performing an angioplasty procedure within a human patient's coronary artery. Also as shown in Figure 3, the XIENCE V RX EECSS has a guidewire lumen length of approximately 30 cm wherein the proximal guidewire opening is approximately 30 cm from the distal end of the catheter shaft. This design allows for rapid exchange capability without utilization of an exchange wire or extension wire – hence the name XIENCE V "Rapid Exchange" EECSS.
a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;	As shown in Figure 3, the XIENCE V RX EECSS has an elongated catheter shaft having a proximal end (left end of catheter) and distal end (right end of catheter). The elongated catheter shaft is percutanteously introduced into the patient's femoral artery, and is thus configured for the same.
b) a distal guidewire opening in the distal end of the catheter shaft;	The XIENCE V RX EECSS has a distal guidewire opening in the distal end of the catheter shaft. For example, Figure 3 depicts a "Tip Entry," which corresponds to a distal guidewire opening in the distal end of the catheter shaft. Figure 5 provides a more detailed view of the distal guidewire opening in the distal end of the catheter shaft.

Limitation From Claim 3 of U.S. Patent No. 5,451,233 ("233 Patent")	Corresponding Feature in the XIENCE V RX EECSS
c) a proximal guidewire opening in the catheter shaft spaced a short distance of at least 10 cm proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;	The XIENCE V RX EECSS has a proximal guidewire opening in the catheter shaft spaced a short distance of at least 10 cm proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft. For example, Figure 4 provides a detailed view of the "Guide Wire Exit Notch" of the XIENCE V RX EECSS, which corresponds to a proximal guidewire opening. Figure 3 shows that the "Guide Wire Exit Notch" is located at least 10 cm, i.e., about 30 cm proximally from (i.e., to the left of) the distal guidewire opening and approximately 110 cm (i.e., "a substantial distance") from the proximal end of the catheter shaft. (Note: Figure 3 is not drawn to scale.)
d) a flexible distal shaft section configured to be advanceable within the patient's coronary arteries	The XIENCE V RX EECSS has a flexible distal shaft section. The flexible distal shaft section (among other things) allows it to navigate tortuous coronary arteries. For example, as shown in Figure 3, the XIENCE V RX EECSS has a flexible distal shaft section extending from the distal guidewire opening (labeled "Tip Entry") to the area of, and including, the proximal guidewire opening (labeled "Guide Wire Exit Notch"). The IFU for the XIENCE V RX EECSS confirms that the distal shaft section is configured to be advanceable within the patient's coronary arteries (see Exhibit E).
having a guidewire-receiving lumen extending proximally from the distal guidewire opening to the proximal guidewire opening and having an inflation lumen coextensive at least in part with the guidewire-receiving lumen,	As shown in Figures 3-5, the flexible distal shaft section of the XIENCE V RX EECSS has a guidewire-receiving lumen that extends proximally from the distal guidewire opening (i.e., the "Tip Entry") to the proximal guidewire opening (i.e., the "Guide Wire Exit Notch"). It also has an inflation lumen that is coextensive at least in part with the guidewire-receiving lumen that allows for inflation of the balloon (as shown in Figures 3-5).

Limitation From Claim 3 of U.S. Patent No. 5,451,233 ("233 Patent")	Corresponding Feature in the XIENCE V RX EECSS
e) an inflatable dilatation balloon on the distal shaft section having proximal and distal ends, having an interior which is in fluid communication with the inflation lumen and being spaced closer to the distal end of the catheter shaft than the proximal guidewire opening; and	The XIENCE V RX EECSS has an inflatable dilatation balloon on the distal shaft section. For example, Figure 5 shows a detailed view of the inflatable dilatation balloon having proximal and distal ends. The inflatable balloon is in fluid communication with the inflation lumen (e.g., the balloon is inflated by communicating fluid through the inflation lumen). Further, as shown in Figure 3, the inflatable balloon is spaced closer to the distal end of the catheter shaft than the proximal guidewire opening (i.e., "the Guide Wire Exit Notch" in Figure 3).
f) a proximal shaft section much longer than the distal shaft section which is an elongated tubular member with an inner lumen extending therein in fluid communication with the inflation lumen in the distal section	The XIENCE V RX EECSS has an elongated proximal shaft section much longer than the distal shaft section. For example, as shown in Figure 3, the XIENCE V RX EECSS has a proximal shaft section comprising a jacketed stainless steel hypotube that is about 110 cm long and much longer than the distal shaft section, which is about 30 cm long. (Note: Figure 3 is not drawn to scale.) The proximal shaft section is an elongated tubular member with an inner lumen extending therein in fluid communication with the inflation lumen in the distal section, as evidenced by the ability to inflate the balloon shown in Figure 3.
and which is suitable to advance the distal shaft section within a patient's coronary artery over a guidewire slidably disposed within the guidewire receiving lumen.	As noted above, the proximal shaft section of the XIENCE V RX EECSS comprises a jacketed stainless steel hypotube and is suitable to advance the distal shaft section within a patient's coronary artery over a guidewire slidably disposed within the guidewire receiving lumen, as discussed in more detail in the IFU (see Exhibit E).

10. A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

* * *

(v) For a patent claiming a medical device:

(A) The effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device, if no IDE was submitted, and any available substantiation of that date;

The effective date of the investigational device exemption (IDE) was **May 4, 2005** (the date on which the XIENCE V EECSS product received conditional approval. The IDE No. for the XIENCE V EECSS product was G050050.

(B) The date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application; and

The application for product approval under Section 515 of the Federal Food, Drug and Cosmetic Act, i.e., the Premarket Approval Application (PMA) was submitted in three modules, with Module 1 initially submitted on **July 14, 2006**. The PMA Number was P070015.

(C) The date on which the application was approved or the protocol declared to be completed; (37 CFR 1.740(a)(10))

The PMA was approved on **July 2, 2008**.

11. A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; (37 CFR 1.740(a)(11))

Attached as Exhibit F is a table listing significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the dates such activities occurred. Further details regarding the marketing applicant's activities during the regulatory review period may be provided upon request.

12. A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined; (37 CFR 1.740(a)(12))

In the opinion of the Applicant, the U.S. Patent No. 5,451,233 is eligible for an extension under 35 U.S.C. § 156 because:

(i) one or more of the claims to U.S. Patent No. 5,451,233 claim the approved product (XIENCE V EECSS);

(ii) the term of U.S. Patent No. 5,451,233 has not been extended on the basis of 35 U.S.C. §156 before submission of the instant application;

(iii) the term of no other U.S. Patent has been extended under 35 U.S.C. § 156 on the basis of the regulatory review process associated with the approved product (XIENCE V EECSS);

(iv) there is an eligible period of regulatory review by which the patent may be extended pursuant to 35 U.S.C. §156;

(v) the present application has been submitted within the 60-day period following the approval date of the approved product, pursuant to 35 U.S.C. § 156(c);

(vi) the owner of the U.S. Patent No. 5,451,233 has authorized the applicant before the FDA for marketing approval to apply for the extension of U.S. Patent No. 5,451,233 patent on his behalf (see Exhibit A); and

(vii) the application submitted herewith otherwise complies with all requirements of 35 U.S.C. §156 and all applicable rules and procedures.

(B) The period which the term of U.S. Patent No. 5,451,233 is requested by the Applicant to be extended is **937 days**, such that the patent would expire on **May 24, 2011**.

(C) The requested period of extension of the term of U.S. Patent No. 5,451,233 corresponds to the regulatory review period that eligible for extension pursuant to 35 U.S.C. §156, as calculated in 37 CFR § 1.777.

1. Calculations under 37 CFR §1.777(c)(1)

The number of days in the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug and Cosmetic Act; **436 days**

2. Calculations under 37 CFR §1.777(c)(2)

The number of days in the period beginning on the date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug and Cosmetic Act, and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) of the Act and ending on the date the protocol was declared completed under section 515(f)(6) of the Act. **719 days**

Total Regulatory Review Period under 37 CFR §1.777(c): **1155 days**

3. Calculations under 37 CFR §1.777(d)(1)

Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period pursuant to paragraph (c) of this section:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

Subtract 0 days

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with

due diligence; **Applicant is believed to have acted with due diligence throughout the regulatory review period; Subtract 0 days**

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction; **Subtract 218 days**

Relevant Period pursuant to 37 CFR §1.777(d)(1): **937 days (1155 days - 218 days)**

3. Calculations under 37 CFR §1.777(d)(2)

By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer; **937 days added to October 29, 2008 is May 24, 2011**

4. Calculations under 37 CFR §1.777(d)(3)

By adding 14 years to the date of approval of the application under section 515 of the Federal Food, Drug and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the Act; **July 2, 2022**

5. Calculations under 37 CFR §1.777(d)(4)

By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date; **May 24, 2011**

6. Calculations under 37 CFR §1.777(d)(5)

If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; **October 29, 2013**

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date; **May 24, 2011**

Applicant submits that U.S. Patent No. 5,451,233 should be extended to **May 24, 2011**.

13. A statement that applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (37 CFR 1.740(a)(13))

Pursuant to 37 CFR. §1.1740(a)(13), applicant acknowledges its duty to disclose to the Director of the PTO and to the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought, particularly as that duty is defined in 37 CFR. § 1.765.

14. The prescribed fee for receiving and acting upon the application for extension (37 CFR 1.740(a)(14))

Please deduct the fee prescribed in 37 CFR §1.20(j) for a patent term extension application under 35 U.S.C. §156 from Deposit Account No. 02-4377.

15. The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed. (37 CFR 1.740(a)(15))

Correspondence in connection with this application shall be directed to:

Daniel J. Hulseberg
USPTO Registration Number 36,554
Customer No. 62,614
30 Rockefeller Plaza
New York, NY 10112-4498
Phone Number: 212.408.2500
Fax Number: 212.408.2501

16. The application under this section must be accompanied by two additional copies of such application (for a total of three copies). (37 CFR 1.740(b))

Applicant submits herewith two additional copies of this application, as required by 37 CFR 1.740(b). Applicant also provides herewith two additional courtesy copies as requested in MPEP § 2753 for a total of five copies.

Respectfully submitted,

Daniel J. Hulseberg
Patent Office Reg. No. 36,554

Attorneys for Applicant
BAKER BOTTS L.L.P.
Customer No. 62,614
30 Rockefeller Plaza
New York, NY 10112-4498
(212) 408-2500

Exhibit A

ACKNOWLEDGMENT AND AGREEMENT

WHEREAS, U.S. Patent No. 5,451,233 ("the 233 Patent") is owned by Paul G. Yock and exclusively licensed to Abbott Cardiovascular Systems, Inc. (hereafter "ACS") according to the terms of an Amended License Agreement and various amendments thereto, the terms of which shall remain confidential;

WHEREAS, absent any legal extension of the term, the 233 Patent expires on October 29, 2008; and

WHEREAS, Paul G. Yock and ACS mutually desire to seek a patent term extension on the 233 Patent under 35 U.S.C. §156 based on the approval by the FDA to market the "XIENCE® V Rapid Exchange (RX) Everolimus Eluting Coronary Stent System" and "XIENCE® V Over-the-Wire (OTW) Everolimus Eluting Coronary Stent System";

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which is hereby acknowledged, I, PAUL G. YOCK, ACKNOWLEDGE AND AGREE THAT:

1. ACS is authorized to act on my behalf to file a Patent Term Extension application ("PTE Application") under 35 U.S.C. §156 to extend the term of the 233 Patent.

2. ACS is acting as my agent in filing such PTE Application, as the term "agent" is used in 37 CFR 1.730(a) and other applicable rules and provisions.

3. I, Paul G. Yock, will and hereby agree to fully cooperate in ACS's efforts in seeking such patent term extension under 35 U.S.C. § 156 for the 233 Patent. Such cooperation includes, but is not limited to, granting Power of Attorney to ACS and/or its choice of counsel to file and prosecute such PTE Application and to sign such instruments as requested or deemed necessary by ACS in its sole discretion to obtain patent term extension for the 233 Patent.

4. This "Acknowledgement and Agreement" is intended to and shall constitute sufficient proof and evidence of ACS's authority to file the PTE Application on my behalf, as referenced in 37 CFR 1.730(c).

IN WITNESS WHEREOF, the undersigned has executed this Acknowledgment and Agreement.

DR. PAUL G. YOCK

By:_____
Dr. Paul G. Yock

Date: 7/21/08

US005451233A

United States Patent [19]

Yock

[11] Patent Number: 5,451,233

[45] Date of Patent: * Sep. 19, 1995

[54] ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES

[76] Inventor: Paul G. Yock, 1216 San Mateo Dr., Menlo Park, Calif. 94025

[*] Notice: The portion of the term of this patent subsequent to Oct. 29, 2008 has been disclaimed.

[21] Appl. No.: 208,972

[22] Filed: Mar. 9, 1994

Related U.S. Application Data

[60] Division of Ser. No. 10,458, Jan. 27, 1993, Pat. No. 5,300,085, and a continuation of Ser. No. 937,977, Nov. 2, 1992, Pat. No. 5,350,395, which is a continuation of Ser. No. 774,479, Oct. 10, 1991, abandoned, which is a continuation of Ser. No. 548,200, Jul. 5, 1990, Pat. No. 5,061,273, which is a continuation of Ser. No. 361,676, Jun. 1, 1989, abandoned, which is a continuation of Ser. No. 117,357, Oct. 27, 1987, abandoned, which is a continuation of Ser. No. 852,197, Apr. 15, 1986, abandoned.

[51] Int. Cl.[6] A61M 25/10

[52] U.S. Cl. 606/194; 606/7; 604/96; 604/264; 128/673

[58] Field of Search 606/194, 192, 193, 191, 606/7, 15; 604/96, 101, 102, 264; 128/673

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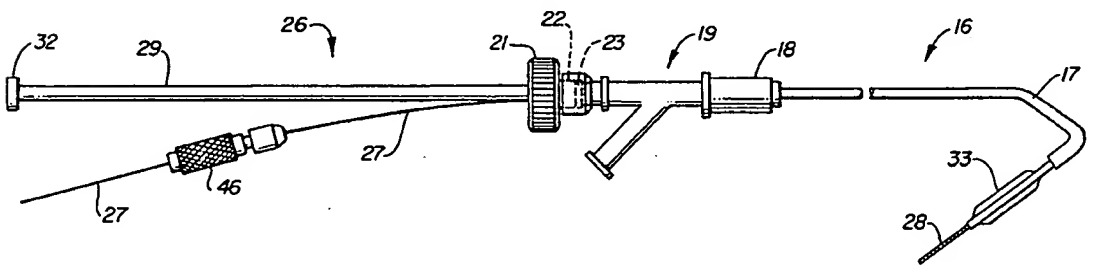
Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—Crosby, Heafey, Roach & May

[57] ABSTRACT

Apparatus for introduction into the vessel of a patient comprising a guiding catheter adapted to be inserted into the vessel of the patient and a device adapted to be inserted into the guiding catheter. The device includes a flexible elongate member and a sleeve carried by the flexible elongate member near the distal extremity thereof and extending from a region near the distal extremity to a region spaced from the distal extremity of the flexible elongate element. The device also includes a guide wire adapted to extend through the sleeve so that the guide wire extends rearwardly of the sleeve extending alongside of and exteriorally of the flexible elongate element into a region near the proximal extremity of the flexible elongate element.

4 Claims, 3 Drawing Sheets



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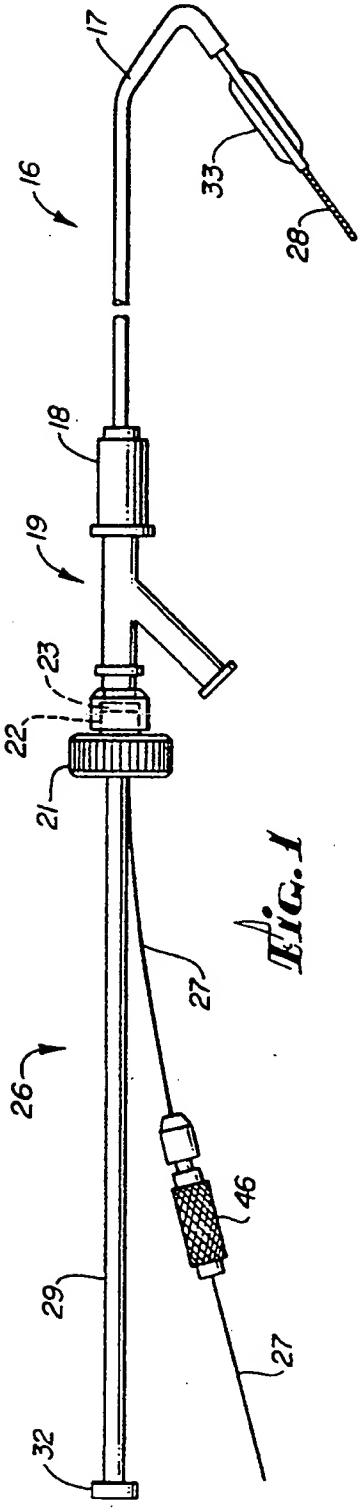

FIG. 1

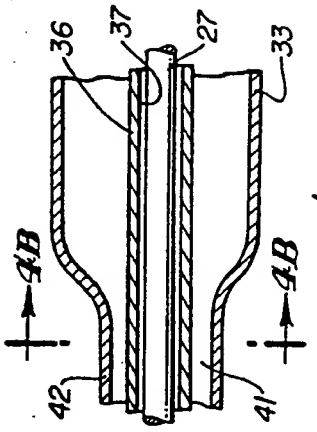

FIG. 4A

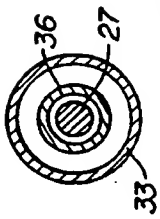

FIG. 4B

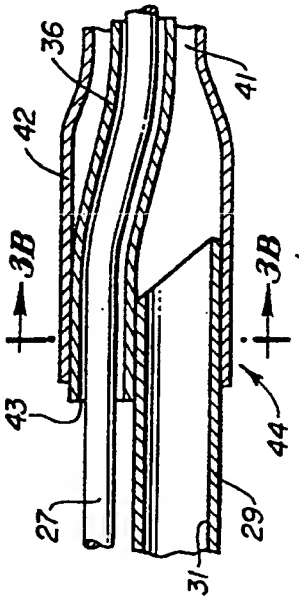

FIG. 3A

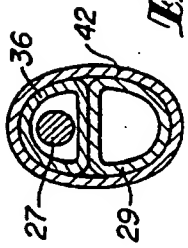

FIG. 3B

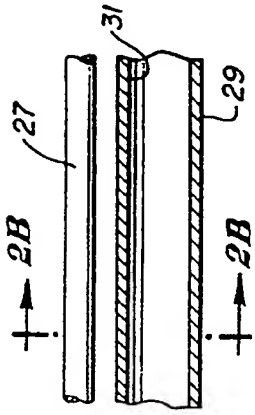

FIG. 2A

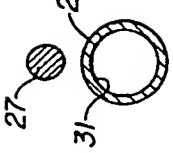

FIG. 2B

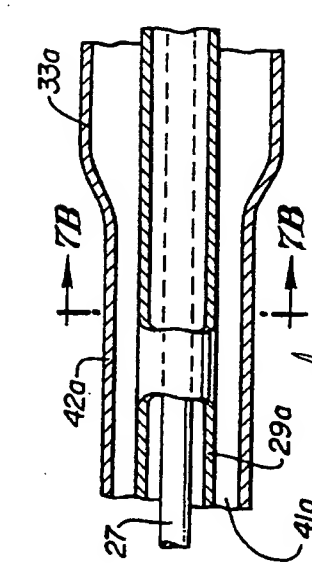

FIG. 7A

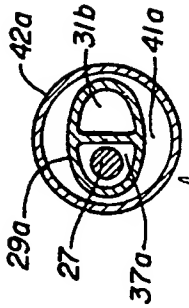

FIG. 7B

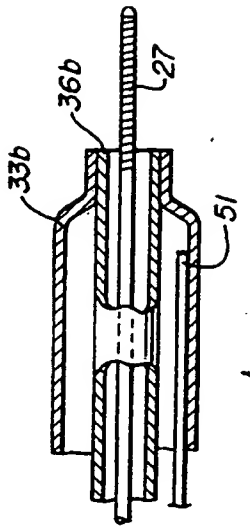

FIG. 9

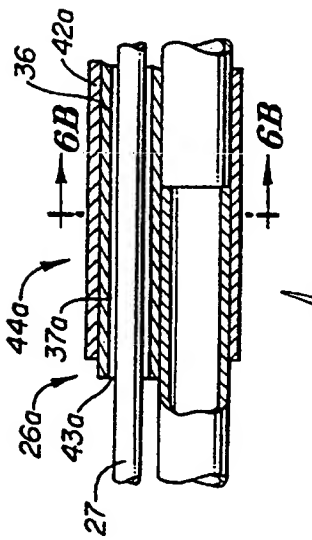

FIG. 6A

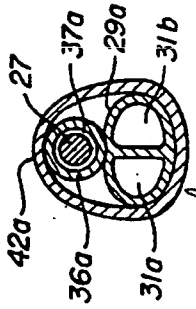

FIG. 6B

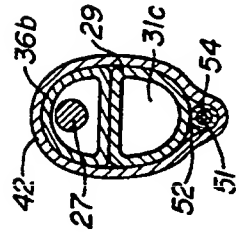

FIG. 8B

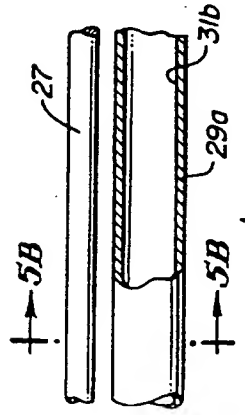

FIG. 5A

FIG. 8A

FIG. 5B

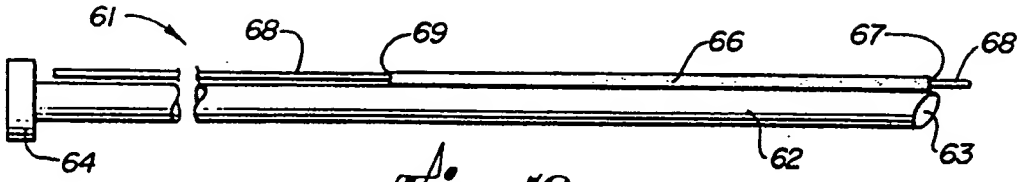

Fig. 10

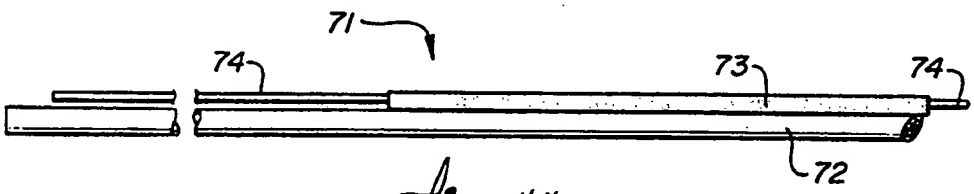

Fig. 11

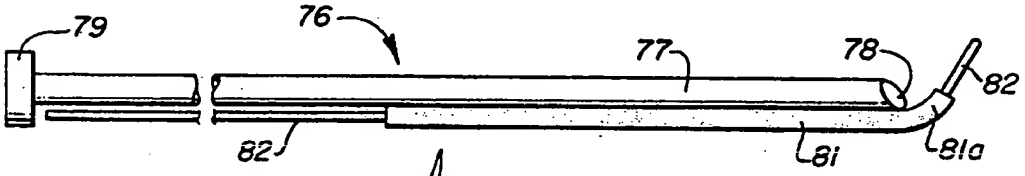

Fig. 12

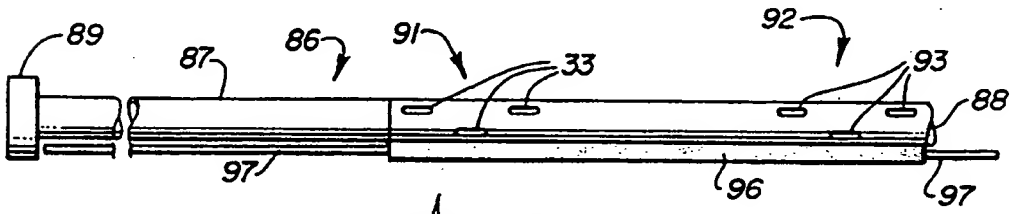

Fig. 13

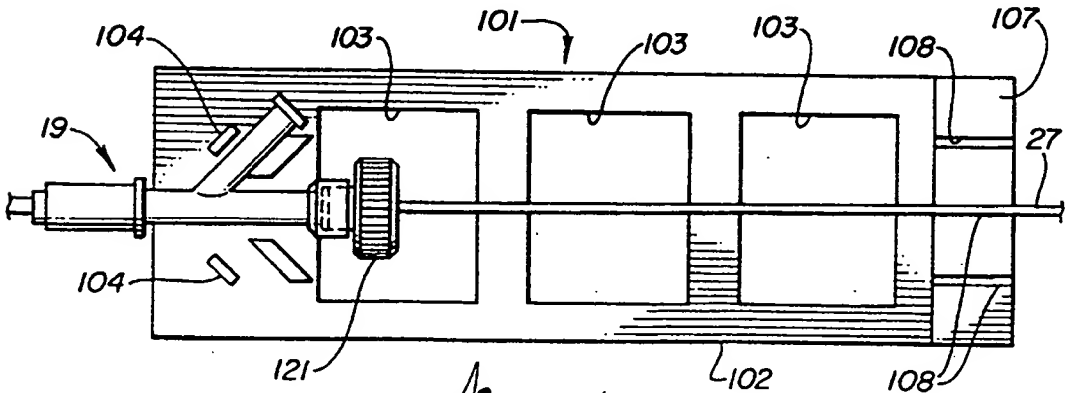

Fig. 14

ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES

This is a divisional application of application of Ser. No. 08/010,458 now U.S. Pat. No. 5,300,085 which was filed on Jan. 27, 1993 and a continuation of Ser. No. 07/937,977 now U.S. Pat. No. 5,350,395 which was filed on Nov. 2, 1992, both of which are continuations of Ser. No. 07/774,479, now abandoned filed Oct. 10, 1991 which is a continuation of Ser. No. 07/548,200 now U.S. Pat. No. 5,061,273 filed Jul. 5, 1990, which is a continuation of Ser. No. 07/361,676 now abandoned filed Jun. 1, 1989 which is a continuation of Ser. No. 07/117,357, now abandoned filed Oct. 27, 1987 which is a continuation of Ser. No. 06/852,197, now abandoned filed Apr. 15, 1986.

This invention relates to angioplasty apparatus facilitating rapid exchanges and a method for making rapid exchanges of angioplasty devices.

At the present time in practicing angioplasty, it is often necessary to exchange one dilatation catheter for another. In doing so, it has been necessary to utilize long exchange wires having a length of approximately 300 centimeters which typically requires two operators to perform the procedure. During this procedure, it is necessary that the operators communicate with each other which makes the procedure time consuming. In addition, since the exchange wire is so long it often is awkward to handle and for that reason may come in contact with the floor or become contaminated which necessitates removing the entire apparatus being utilized for the angioplasty procedure. There is therefore a need for a new and improved angioplasty apparatus which overcomes such difficulties.

In general, it is an object of the present invention to provide an angioplasty apparatus and a method which facilitates rapid exchanges of various types of devices.

Another object of the invention is to provide an angioplasty apparatus and method of the above character which greatly facilitates exchanges of dilatation catheters.

Another object of the invention is to provide an angioplasty apparatus and method of the above character which can be utilized for the positioning of flexible elongate members.

Another object of the invention is to provide an angioplasty apparatus and method of the above character which can be utilized with various types of devices utilizing flexible elongate members.

Another object of the invention is to provide an angioplasty apparatus and method in which dye injection and pressure measurements can be made.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in conjunction with the accompanying drawings.

FIG. 1 is a side elevational view of an angioplasty apparatus incorporating the present invention.

FIGS. 2A, 3A and 4A are partial cross sectional views of the shaft, transition and balloon regions of the balloon dilatation catheter utilized in the embodidment of the invention shown in FIG. 1.

FIGS. 2B, 3B and 4B are cross sectional views taken along the lines 2B—2B, 3B—3B and 4B—4B of FIGS. 2A, 3A and 4A respectively.

FIGS. 5A, 6A and 7A are cross sectional views corresponding to FIGS. 2A, 3A and 4A of another embodiment of a balloon dilatation catheter incorporating the present invention.

FIGS. 5B, 6B and 7B are cross sectional views taken along the lines 5B—5B, 6B—6B and 7B—7B of FIGS. 5A, 6A and 7A respectively.

FIGS. 8A and 9 are cross sectional views of the transition and balloon regions of another balloon dilatation catheter incorporating the present invention.

FIG. 8B is a cross sectional view taken along the line 8B—8B of FIG. 8A.

FIG. 10 is a side elevational view of a dedicated dye injection/pressure measurement catheter incorporating the present invention.

FIG. 11 is a side elevational view of a fiber optic cable incorporating the present invention.

FIG. 12 is a side elevational view of a dedicated dye injection/pressure measurement catheter incorporating the present invention and having specific guiding means for facilitating entering acute bends in arterial vessels.

FIG. 13 is a side elevational view of a bail out catheter incorporating the present invention.

FIG. 14 is a plan view of a holder utilized in connection with the present invention.

In general, the angioplasty apparatus of the present invention is designed for introduction into the vessel of a patient. It consists of a guiding catheter which is adapted to be inserted into the vessel of the patient. It also consists of a device which is adapted to be inserted into the guiding catheter. The device includes a flexible elongate member, a sleeve is secured to the flexible elongate member near the distal extremity thereof and extends from the distal extremity into a region spaced from the distal extremity of the flexible elongate member. The device also includes a guide wire which is adapted to extend through the sleeve from the distal extremity of the flexible elongate element, through the sleeve and rearwardly of the sleeve alongside of and exteriorally of the flexible elongate element.

More particularly as shown in FIGS. 1–4, the angioplasty apparatus 16 for facilitating rapid exchanges of dilatation catheters consists of a conventional guiding catheter 17 which is provided with a rotatable hemostatic adapter 18 mounted on a proximal end and a y or two-arm connector or adapter 19 which is mounted on the rotatable adapter 18. The y-connector 19 is provided with a knurled knob 21 which carries a threaded valve member 22 that carries an O-ring 23 which is adapted to be urged into sealing engagement with a balloon dilatation catheter 26 and a guide wire 27 extending through the y-adapter 19 and through the guiding catheter 17 as shown in FIG. 1.

The balloon dilatation catheter 26 is of a single lumen type and is provided with a flexible elongate tubular member 29 which has a lumen 31 extending therethrough. The flexible tubular member 29 can be formed of a suitable material such as plastic. A Luer-type fitting 32 is mounted on the proximal extremity of the flexible tubular member 29 and is adapted to be connected to a syringe or other type of instrument for introducing a radiographic contrast liquid into the flexible tubular member 29. A balloon 33 is mounted on the distal extremity of another flexible tubular member 36 also is formed of a suitable material such as plastic. The distal extremity of the balloon 33 is bonded to the distal extremity of the flexible tubular member 36 to form an air-tight and liquid-tight seal with respect to the same. The balloon 33 is coaxial with the tubular member 36 or sleeve as shown in FIG. 4B. The flexible tubular mem-

ber 36 is provided with a guide wire lumen 37 through which the guide wire 27 carrying its flexible tip 28 can extend.

Means is provided for forming a balloon inflation lumen 41 substantially concentric with the flexible tubular member 36 and extends toward the distal extremity of the flexible tubular member 36. As can be seen from FIGS. 3B and 4B, the balloon inflation lumen 41 is formed by a flexible tubular member 42 which can be formed integral with the balloon 33. The flexible tubular member 42 extends into a transition region 44 which overlies the distal extremity of the flexible tubular member 29 so that the lumen 31 therein is in communication with the balloon inflation lumen 41. As can be seen particularly from FIG. 3A, the flexible tubular member 36 makes a transition and extends out of the tubular member 42 and provides an opening 43. The proximal extremity of the tubular member 36 overlies the flexible tubular member 31. The guide wire 27 exits through the opening 43 and extends alongside and exteriorally of the flexible tubular member 29 from the proximal extremity of the flexible tubular member 36 to the proximal extremity of the flexible tubular member 29.

The transition region 44 should be positioned at least approximately 10–15 centimeters from the distal extremity of the balloon dilatation catheter 26. This is important for two reasons. One is that the transition region be kept at a point where when the balloon dilatation catheter 26 is utilized in a procedure, the transition region remains in the guiding catheter 27 and out of the coronary artery. The spacing from the distal extremity of the dilatation catheter for the transition region is also advantageous in that it permits the person performing the procedure to pull the balloon dilatation catheter 26 out of the guiding catheter 17 until the transition region 44 clears the y-connector 19 so that all of the portion of the guide wire 27 which is exterior of the balloon dilatation catheter 26 is proximal of the y-connector. While this is being done, the operator can then utilize the knurled nut 21 to again close the o-ring to form a hemostatic seal between the y-connector and the balloon dilatation catheter to minimize the loss of blood from the patient.

The flexible tubular member 42 can be formed of a suitable material such as a heat shrinkable plastic so that it can be shrunk onto the distal extremity of the flexible tubular member 29 and onto the proximal extremity of the flexible tubular member 36 to form liquid-tight and air-tight seals with respect to the same. From the construction shown it can be seen that the guide wire 27 exits from the balloon dilatation catheter 26 in a region which is relatively close to the distal extremity of the balloon dilatation catheter 26 and extends exteriorally of the balloon dilatation catheter to the proximal extremity of the same. As shown in FIG. 1, the guide wire 27 and the balloon dilatation catheter 26 extend outwardly from the y-connector 19.

A torquer 46 of a conventional construction is secured to the guide wire 27 for rotating the guide wire as hereinafter described.

Operation and use of the angioplasty apparatus shown in FIG. 1 may now be briefly described as follows. The guiding catheter 17 is inserted into the coronary artery in a conventional manner. The balloon dilatation catheter is prepared for insertion into the guiding catheter 17 in a conventional manner. The balloon 33 can be inflated outside the body by the use of a balloon flushing tube of the type described in U.S. Pat. No. 4,323,071 and inflated by introducing a radiopaque liquid through the fitting 32 into the lumen 31 and through the lumen 41 into the balloon 33 to flush all of the air in the balloon 33 through the balloon flushing tube to fully inflate the balloon. After the balloon 33 has been inflated, the balloon can be deflated by removing the radiopaque liquid from the balloon.

The guide wire 27 is then introduced into the balloon dilatation catheter 26 by a back loading technique. Without the torquer 46 on the guide wire, the proximal extremity of the guide wire 27 is inserted backwardly through the tip of the balloon dilatation catheter through the guide wire lumen 37. The guide wire is advanced rearwardly by holding the distal extremity of the balloon dilatation catheter in one hand and advancing the guide wire 27 rearwardly with the other hand until the guide wire 27 exits through the opening 43 at the transition region 44 of the dilatation catheter. As soon as the guide wire has cleared the opening 43, the guide wire can be grasped by the hand and pulled rearwardly paralleling the balloon dilatation catheter 26 until its proximal extremity is near the proximal extremity of the dilatation catheter and so that the distal extremity of the guide wire 27 with its flexible or floppy tip 28 protrudes at least partially from the distal extremity of the balloon dilatation catheter.

At this point in time, the O-ring 23 in the y-connector 19 is opened by operation of the knurled knob 21. The distal extremity of the balloon dilatation catheter 26 having the flexible tip protruding therefrom is then introduced to the y-connector past the opened o-ring 23 and slid down the guiding catheter 17. The balloon dilatation catheter 26 and the guide wire 27 are grasped between the fingers of a hand and are advanced parallel into the guiding catheter 17. This procedure is continued until a substantial portion of the balloon dilatation catheter is disposed in the guiding catheter 17.

The torquer 46 now can be attached to the guide wire 27 near the proximal extremity of the same. The guide wire 27 is then advanced ahead of the balloon dilatation catheter until it enters the arterial vessel of the patient. The balloon dilatation catheter 26 is held stable by the fingers of the hand while the guide wire 27 is being advanced. The positioning of the guide wire 27 in the desired arterial vessel can be observed under a fluoroscope by using x-ray techniques well known to those skilled in the art. As is well known to those skilled in the art, the torquer 46 can be utilized for rotating the guide wire 27 to facilitate positioning of the flexible tip 28 in the desired arterial vessel so that the distal extremity of the guide wire can be advanced into the stenosis which it is desired to open or enlarge.

As soon as the guide wire 27 is in the desired location, it can be held stationary by two fingers of the hand and at this point in time, the balloon dilatation catheter 26 is advanced over the guide wire until the deflated balloon 33 is across the desired lesion or stenosis. If any difficulty is encountered by the person conducting the procedure in introducing the balloon dilatation catheter so that the balloon 33 resists crossing the lesion or stenosis, the guide wire 27 can be retracted slightly. The person then can observe under the fluoroscope to see that the tip 28 of the guide wire is wiggling in the blood stream indicating that it is free to move in the blood stream. Then the person can grasp both the guide wire and the dilatation catheter in one hand and advance them as a unit so that they can cross the stenosis as a unit. It has been found by utilizing such a procedure, greater pusha-

bility can be obtained in advancing the balloon dilatation catheter across the stenosis. In other words, more force can be applied to the balloon to cause it to cross the stenosis or lesion in case the opening therein is very small.

After the balloon **33** has crossed the stenosis or lesion, the balloon **33** can be inflated in a conventional manner by introducing a radiopaque contrast liquid through the lumen **31**. After the inflation has occurred and the desired operation has been performed by enlarging the opening in the stenosis, the balloon dilatation catheter **26** can be removed very rapidly by the person performing the procedure by grasping the guide wire **27** by two fingers immediately proximal of the y-connector **19** after the torquer **46** has been removed. The balloon dilatation catheter **26** can be removed in several seconds in comparison with the much longer time required for removing the balloon dilatation catheter utilizing prior art exchange wire procedures. As soon as the balloon dilatation catheter **26** has been removed from the guiding catheter **17**, another injection of radiographic contrast liquid can be introduced through the guiding catheter **17** to observe whether or not the balloon dilatation procedure which has been performed on the lesion or stenosis has in fact opened the lesion or stenosis to the satisfaction of the person performing the procedure.

If it is ascertained by the person performing the procedure that additional dilation of the stenosis is desired and that a larger balloon should be inserted into the stenosis, this can be accomplished very rapidly by selecting the desired size of balloon dilatation catheter.

As the balloon dilatation catheter **26** is being retracted out of the guiding catheter **17** and as soon as the transition region **44** has cleared the y-adapter **19**, the o-ring **23** can be tightened down to form a seal over the balloon dilatation catheter to minimize the loss of blood of the patient. Thereafter, if desired, the remainder of the balloon dilatation catheter **26** can be removed from the guiding catheter **17** until the proximal extremity of the guide wire passes through the opening **43** and passes through the end of the balloon dilatation catheter **26**. As soon as this has been accomplished, a new balloon dilatation catheter can be loaded onto the guide wire in a rearward direction by introducing the proximal extremity of the guide wire **27** into the tip of the balloon dilatation catheter. As this is being done, the index finger of the hand performing the procedure can be utilized for opening the o-ring by adjusting the knurled knob **21**. The guide wire **27** is grasped by the fingers of the hand and the balloon dilatation catheter **26** can be advanced rapidly over the guide wire into the guiding catheter **17** and advanced across the lesion in a manner hereinbefore described with respect to the smaller balloon dilatation catheter which had been utilized. The balloon of the new dilatation catheter can be inflated in the same manner as hereinbefore described. If necessary even another exchange procedure can be readily accomplished in the same manner as hereinbefore described utilizing a still larger balloon dilatation catheter if that turns out to be necessary.

It has been found that an exchange utilizing the present angioplasty apparatus can be performed in less than 10 to 15 seconds whereas in the past utilizing a prior art guide wire exchange procedure required an average of approximately two minutes.

After the desired amount of dilation of the stenosis or lesion has been accomplished, the balloon dilatation catheter **26** can be removed and thereafter, the guiding catheter **17** can be removed.

Another embodiment of an angioplasty apparatus incorporating the present invention is shown in FIGS. **5A** and **5B**, **6A** and **6B** and **7A** and **7B** in which an additional dye/pressure lumen has been incorporated into the apparatus in order to enable an injection of a distal dye through the balloon dilatation catheter and also to enable the measurement of pressures at the tip of the balloon dilatation catheter. The construction which is utilized is very similar to that shown in the balloon dilatation catheter **26** shown in FIG. **1**. The corresponding parts of the balloon dilatation catheter **26*a*** shown in FIGS. **5–7** is very similar to that hereinbefore described and for that reason the corresponding parts have been given the same corresponding numbers with letters being added to the numerals where changes are present in the parts or components. Thus the tubular member **29*a***, rather than having a single lumen **31** is provided with dual lumens **31*a*** and **31*b*** disposed side by side in the shaft region of the balloon dilatation catheter as shown in FIGS. **5A** and **5B**. In the transition region **44*a***, the two lumens **31*a*** and **31*b*** are still disposed side by side with the lumen **37*a*** for the guide wire being disposed above the lumens **31*a*** and **31*b***. In the balloon region, the lumen **31*a*** has been terminated and extends into the balloon lumen **41*a***. At the transition region **44*a***, the guide wire lumen **37*a*** inclines downwardly and sidewise and adjoins the lumen **31*b*** through the distal extremity of the balloon dilatation catheter **26*a***. The lumen **31*b*** extends to the distal extremity of the balloon dilatation catheter.

The balloon dilatation catheter which is shown in FIGS. **5–7** can be utilized in the same manner as the balloon dilatation catheter shown in FIG. **1**. It can be seen that the guide wire **27** extends out of the opening **43*a*** in the transition region **4*c*** and parallels the balloon catheter to its proximal extremity. A balloon dilatation catheter of the type shown in FIGS. **5–7** can be utilized initially in an angioplasty procedure. However, it should be appreciated that if a very small opening is present in the stenosis or lesion, it may be desirable to utilize a balloon dilatation catheter of the type shown in FIG. **1** first because it can be constructed with a smaller diameter than a balloon dilatation catheter of the type shown in FIGS. **5–7** because of the additional lumen which is provided for dye injection and pressure measurements. After a smaller balloon dilatation catheter has been utilized, a balloon dilatation catheter of the type shown in FIGS. **5–7** can be used utilizing the exchange procedure hereinbefore described to make dye injection and/or pressure measurements through the use of the additional lumen **31*b***. It is particularly desirable to make such a pressure measurement before conclusion of the angioplasty procedure to be sure that the proper dilation of the lesion or stenosis has occurred and that there is adequate blood flow through the lesion or stenosis.

Still another embodiment of the angioplasty apparatus incorporating the present invention is shown in FIGS. **8A** and **8B** and shows the transition region of a balloon dilatation catheter **26b** which incorporates a vent tube **51** which is utilized for venting air from the balloon during inflation of the balloon and before insertion into the patient with radiopaque liquid to ensure that all the air is exhausted from the balloon. As shown in the transition region **44b** in FIG. **8A**, the guide wire **27** extends through an opening **43*b*** provided in the

transition region and extends through a flexible tubular member 36*b* out the end of the balloon dilatation catheter as shown in FIG. 9. A balloon filling lumen 31*c* is provided by the flexible tubular member 29*b* and terminates in the transition region 44*b* where it opens into the balloon filling lumen 41*b* that opens into the interior of the balloon 33*b*. A relatively short sleeve 52 formed of a suitable material such as plastic is also provided in the transition region 44*b* and as shown in FIG. 8A underlies the flexible tubular member 29*b* and extends from a region forward of the flexible tubular member 42*b* and terminates distally within the balloon inflation lumen 41 as shown in FIG. 8A.

The sleeve 52 is provided with a lumen 53 through which the vent tube 51 extends. The vent tube 51 can be formed of a suitable material such as metal and is also provided with a lumen 54 of a size so that gas can escape therethrough. The proximal extremity of the vent tube 51 is provided with a portion 51*a* which is bent at right angles to the main portion of the vent tube 51 to ensure that the vent tube will be removed from the balloon dilatation catheter 26*b* prior to insertion into the guiding catheter 17. As shown in FIG. 9, the vent tube 51 extends into the balloon 33 into a region near the distal extremity of the same.

Operation of the balloon dilatation catheter 26*b* shown in FIGS. 8A, 8B and 9 may now be briefly described as follows. With the vent tube 51 in place in the balloon dilatation catheter, radiopaque contrast liquid is introduced through the balloon inflation lumen 31 and through the balloon inflation lumen 41*b* to introduce the liquid into the balloon. As the liquid is introduced into the balloon, any air in the balloon is discharged through the vent tube 51. Pressure is maintained on the radiopaque contrast liquid introduced into the balloon until droplets 56 of the liquid exit from the proximal extremity of the vent tube 51 which serves to indicate that the balloon has been completely filled with the radiopaque contrast liquid and that all of the air therein has been exhausted therefrom. As soon as this occurs, the vent tube 51 can be withdrawn completely from the balloon dilatation catheter. The sleeve 52 which carries the vent tube collapses upon withdrawal of the vent tube and will remain collapsed to provide a valve to prevent the escape of any additional radiopaque contrast liquid from the balloon 33*b*. The sleeve 52 remains collapsed because when a high pressure is being introduced through the balloon inflation lumen 31*c*, the flexible tubular member 29*b* will force collapsing of the sleeve 52. Alternatively, when a negative pressure is being applied to the balloon 33*b* as, for example, when the balloon is being deflated, the positive atmospheric pressure on the exterior of the flexible tubular member 42*b* will again cause collapsing of the sleeve 52. Thus in effect there is provided a double valve system in which positive pressures on the interior will collapse the sleeve and when there is negative internal pressure the positive exterior atmospheric pressure will collapse the sleeve.

In all other respects, the balloon dilatation catheter 26*b* can be utilized in the same manner as the balloon dilatation catheters hereinbefore described in connection with exchanges on the guide wire 27.

Still another embodiment of an angioplasty apparatus incorporating the present invention is shown in FIG. 10 in which there is disclosed a dedicated pressure/dye catheter 61. The pressure/dye catheter 61 consists of an elongate flexible tubular member 62 formed of a suitable material such as plastic which is provided with a pressure dye lumen 63 extending therethrough. The proximal extremity of the tubular member 62 is provided with a Luer-type fitting 64 to which devices having Luer-type fittings can be attached. A sleeve 66 formed of a suitable material such as plastic is secured to the exterior of the flexible tubular member 62 by suitable means such as an adhesive. It is provided with a guide wire lumen 67 extending therethrough. It should be appreciated that the sleeve 66 can be formed integral with the flexible tubular member 62 if desired. The sleeve 66 extends for a distance of at least 10 to 15 centimeters from the distal extremity of the catheter 61 so that the transition region where it terminates at its proximal extremity is be within the guiding catheter 17 so that the transition region does not enter into the arterial vessel of the patient. A guide wire 68 is provided which extends through the guide wire lumen 67. The guide wire 68 can be of the same type as the guide wire 27. It is inserted into the sleeve 66 by taking the proximal extremity of the guide wire which is relatively stiff and inserting it into the distal extremity of the sleeve and then pushing it backwardly or rearwardly through the sleeve until it clears the opening 69 at the proximal extremity of the sleeve 66. The guide wire 68 is then pulled so that it extends in a direction parallel to the flexible tubular member 62 into a region near the proximal extremity of the tubular member 62.

It can be readily seen from the foregoing description that the pressure/dye catheter 61 can be readily introduced into a guiding catheter 17 and that the distal extremity of the pressure/dye catheter can be positioned in a desired location in the arterial vessel by utilizing the guide wire 68 to position the same. It also should be appreciated that a torquer of the type hereinbefore described such as the torquer 46 can be utilized on the proximal extremity of the guide wire 68 to cause rotational movement of the guide wire to facilitate positioning of the guide wire in the desired arterial vessel and to thereafter have the tubular member 62 follow the same. The desired picture and/or dye measurements can then be made by utilizing the lumen 63 provided in the tubular member 62. As can be seen from FIG. 10 the distal extremity of the tubular member 62 can be slanted and rounded as shown to facilitate entry into the stenosis in the arterial vessel. This is desirable because of the eccentricity created by the addition of the sleeve 66.

Another embodiment of an angioplasty apparatus is shown in FIG. 11 and takes the form of a fiber optic device 71. An encased fiber optic bundle 72 which is generally circular in cross section is provided. A sleeve 73 of the type hereinbefore described formed of a suitable material such as plastic is secured to the distal extremity of the fiber optic bundle 72 which is adapted to receive a guide wire 74. As in the previous embodiments, the sleeve 73 extends from the distal extremity for a distance of approximately 10 to 15 centimeters after which the guide wire exits from the sleeve and extends alongside and exteriorally of the fiber optic bundle 72 for substantially the entire length of the fiber optic bundle. As with the previous devices, the guide wire 74 is threaded into the sleeve by taking the proximal extremity or stiff end of the guide wire and inserting it at the distal extremity of the sleeve 73 and pushing it from the rear towards the forward extremity of the sleeve. The fiber optic device 71 can then be inserted into a guiding catheter 17 and advanced to the desired location through the use of the guide wire. The fiber optic bundle then can be utilized for angioscopy for

looking directly at the blood vessel or alternatively, for delivering energy to plaque in the blood vessel to perform laser angioplasty. It should be appreciated that steerable systems can be utilized for directing the distal extremity of the fiber optic bundle if that is desired.

It should be appreciated that the concept of using a relatively short sleeve extending from the distal extremity of the device to a region approximately 10 to 15 centimeters to the rear and then having the guide wire extend externally of the device is applicable for a number of medical devices as well as other applications. For example, ultrasonic catheters for imaging ultrasound and for measurement of Doppler velocity can be utilized to provide various types of dedicated devices having the guide sleeve with the guide wire therein for facilitating positioning of the same in arterial vessels. The apparatus of the present invention is particularly useful in devices where multiple re-entries are required in order to complete the procedure.

In FIG. 12, there is disclosed another embodiment of an angioplasty apparatus to provide a pressure dye catheter 76 having additional steering capabilities. It consists of a flexible tubular member 77 formed of a suitable material such as plastic which is provided with a lumen 78 extending through a slanted and curved end. A Luer-type fitting 79 is provided on the proximal extremity. A sleeve 81 formed of a suitable material such as plastic is secured to the distal extremity of the flexible elongate member 77. The sleeve is provided with a curved portion 81*a* which extends slightly beyond the distal extremity of the flexible elongate member 77 and curves over the end of the flexible elongate member 77. The guide wire 82 extends through the sleeve 81 as shown. The catheter shown in FIG. 12 can be utilized in situations where there is an acute bend in the arterial vessel. By using the catheter shown in FIG. 11, the guide wire can be directed into the acute bend by rotation of the catheter 76 to help direct the guide wire into the acute bend. After the acute bend has been negotiated by the guide wire, the distal extremity of the catheter can follow the guide wire and negotiate the acute bend. The desired pressure and/or dye measurements can then be made. If by chance a guide wire should enter the wrong vessel, the guide wire can be retracted into the sleeve and then the catheter itself can be reoriented to have the distal extremity of the sleeve 81 directed into the proper region so that the guide wire will enter the proper arterial vessel. The catheter 76 shown in FIG. 12 can be introduced into the guiding catheter 17 in the same manner as the other catheters hereinbefore described.

Still another embodiment of the angioplasty apparatus of the present invention is shown in FIG. 13 in the form of a bailout catheter 86. The bailout catheter 86 consists of a flexible tubular member 87 formed of a suitable material such as plastic which is provided with a lumen 88 extending therethrough. A Luer-type fitting 89 is secured to the proximal extremity of the tubular member 87. The distal portion of the tubular member 87 is provided with two sets 91 and 92 of holes 93 which are spaced circumferentially and apart longitudinally of the tubular member. A sleeve 96 formed of a suitable material such as plastic is secured to the distal extremity of the tubular member 87 and extends from the distal extremity of the tubular member 87 into a region 10 to 15 centimeters from the distal extremity and is adapted to receive a guide wire 97 which extends through the same. The guide wire 97 is inserted into the sleeve by taking the proximal extremity of the guide wire and inserting it into the distal extremity of the sleeve and pushing it rearwardly into the sleeve until it exits from the sleeve. The guide wire 97 is then pulled in a direction generally parallel to the flexible tubular member 87 until it is adjacent the fitting 89.

The bailout catheter 86 is utilized in situations where an obstruction has occurred in a blood vessel and stops the flow of blood. In order to reestablish the flow of blood, the bailout device is inserted into the guiding catheter 17. If a guide wire is already in place, the bailout device can be placed on the guide wire by introducing the proximal extremity of the guide wire into the sleeve and then pushing the bailout catheter on the guide wire into the guiding catheter 17 until it passes through the obstruction in the arterial vessel. The distal extremity of the bailout device is so positioned so that the obstruction is disposed between the two sets of holes 91 and 92. When the bailout catheter is positioned, blood can still flow through the holes 93 past the obstruction which is held out of the way by the bailout catheter.

Thus it can be seen that the same principle utilizing a guide tube and an external guide wire passing through the guide tube can be utilized for positioning the bailout device. As pointed out previously, the bailout device can be utilized for positioning other types of devices in arterial vessel, as for example, atherectomy devices particularly where multiple re-entries or reintroductions of the devices are required.

In FIG. 14 there is disclosed additional angioplasty apparatus in which a holder 101 is provided which serves as a support structure for a y-type connector 19 of the type hereinbefore described in conjunction with the angioplasty apparatus shown in FIG. 1. The holder 101 consists of a rectangular member 102 which is generally planar. The member 102 can be formed of a suitable material such as plastic and is provided with a plurality of rectangular openings 103 extending longitudinally of the same to lighten the same. Posts 104 are provided on the forward extremity of the member 102 and are adapted to receive the y-type connector 19 and to hold it in place on the member 102. When positioned in the posts 104, the knurled knob 21 extends into one of the openings 103 so that it can be readily operated. A block 107 is carried by the other end of the member 102 and, if desired, can be formed intergal therewith. The block is provided with a plurality of spaced apart slots 108 which are adapted to frictionally engage and receive the guide wire 27. The friction block 107 should be positioned a suitable distance as, for example, 15 to 20 centimeters from the o-ring carried by the y-connector 19.

Use of the holder 101 shown in FIG. 14 may now be briefly described as follows. The holder 101 can be placed on the operating table near the region where the guiding catheter 17 has been inserted into the patient, as for example, in a femoral artery in the leg of a patient. After the guide wire has been inserted into the guiding catheter, the proximal end or, in other words, the stiff end of the guide wire can be placed in the friction clamp 108. When it is desired to utilize a dilatation catheter, the end of the guide wire which has been positioned in the clamp can be lifted out of the slot 108 and inserted into the sleeve carried by the distal extremity of the dilatation catheter by taking the proximal end and advancing it from the tip rearwardly through the sleeve. As soon as the guide wire has been introduced through the sleeve, the proximal extremity of the guide wire can

be repositioned in the slot **108**. Thereafter, the dilatation catheter can be advanced independently without the operator needing to pay any attention to the guide wire which is held in the desired position by the holder **101**. Similarly, the holder can be utilized to keep the guide wire in place while the dilatation cathether is being briskly withdrawn.

More than one of the slots **108** has been provided in the holder **101** in order to make it possible to accommodate two wire or two balloon dilatation catheters in which one of the other slots **108** can be utilized for accommodating the additional guide wire. This prevents the guide wires from becoming entangled with each other.

It is apparent from the foregoing that there has been provided an angioplasty apparatus which greatly facilitates the exchange of devices which utilize flexible elongate elements as a part thereof. Rapid exchanges are possible with only one person being necessary to make the exchanges. The need for long exchange wires has been eliminated. One device can be readily substituted for another utilizing the same guide wire which has already been positioned. It can be seen from the foregoing that a relatively simple and expedient solution has been provided which eliminates the need for long exchange wires and the danger of those exchange wires becoming contaminated.

Although the present invention has been described principally in conjunction with catheters having coaxial lumens, it should be appreciated that the invention is as applicable, if not more applicable, to catheters having side-by-side lumens.

What is claimed is:

1. An elongated intravascular assembly for performing a procedure at a location within a human patient's coronary artery including a guidewire and a catheter which is adapted for rapid exchange over the guidewire without the utilization of an exchange wire or an extension wire, the assembly comprising:

a) an elongated catheter with a catheter shaft which has proximal and distal ends, which is configured for percutaneous introduction into and advancement within the patient's vasculature, which is sufficiently long to be advanced through the patient's femoral artery and into the patient's coronary artery and which has,

a distal shaft section which is configured for advancement within the patient's coronary artery,

a distal guidewire opening in the distal end of the catheter shaft,

a proximal guidewire opening spaced a relatively short distance proximally from the distal guidewire opening and a relatively long distance from the proximal end of the catheter shaft,

an inner lumen which extends between the distal guidewire opening and the proximal guidewire opening and which is configured to slidably receive a guidewire therein, and

a proximal shaft section much longer than the distal shaft section;

b) means on the distal shaft section to perform an intravascular procedure which is spaced closer to the distal guidewire opening than the proximal guidewire opening; and

c) a guidewire which is longer than the catheter to extend out of the distal end of the catheter into the patient's coronary artery beyond the location therein where the procedure is to be performed and which is slidably disposed within the inner lumen extending between the distal guidewire opening and the proximal guidewire opening.

2. An elongated balloon dilatation catheter assembly for performing an angioplasty procedure at a location within a human patient's coronary artery including a guidewire and balloon dilatation catheter which has means for the rapid exchange over the guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) the elongated balloon dilatation catheter being configured for percutaneous introduction into the patient's femoral artery and advancement into the patient's coronary artery and having

an elongated catheter shaft with proximal and distal ends, an inflation lumen and a guidewire receiving lumen,

a distal guidewire opening in the distal end of the catheter shaft in fluid communication with the guidewire lumen,

a proximal guidewire opening spaced a short distance proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft and in fluid communication with the guidewire lumen;

an inflatable dilatation balloon on a distal shaft section having proximal and distal ends, with the distal end of the balloon being spaced closer to the distal guidewire opening than the proximal end of the balloon is spaced from the proximal guidewire opening, and having an interior which is in fluid communication with the inflation lumen; and

b) the guidewire being sufficiently long to be advanced through the patient's femoral artery and into the patient's coronary artery beyond the location therein where the angioplasty procedure is to be performed and being slidably disposed within the guidewire lumen of the balloon dilatation catheter.

3. An elongated balloon dilatation catheter for performing an angioplasty procedure within a human patient's coronary artery which has means for the rapid exchange of the catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;

b) a distal guidewire opening in the distal end of the catheter shaft;

c) a proximal guidewire opening in the catheter shaft spaced a short distance of at least 10 cm proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;

d) a flexible distal shaft section configured to be advanceable within the patient's coronary arteries having a guidewire-receiving lumen extending proximally from the distal guidewire opening to the proximal guidewire opening and having an inflation lumen coextensive at least in part with the guidewire-receiving lumen,

e) an inflatable dilatation balloon on the distal shaft section having proximal and distal ends, having an interior which is in fluid communication with the inflation lumen and being spaced closer to the distal

end of the catheter shaft than the proximal guidewire opening; and

f) a proximal shaft section much longer than the distal shaft section which is an elongated tubular member with an inner lumen extending therein in fluid communication with the inflation lumen in the distal section and which is suitable to advance the distal shaft section within a patient's coronary artery over a guidewire slidably disposed within the guidewire receiving lumen.

4. An elongated balloon dilatation catheter for performing an angioplasty procedure within a human patient's coronary artery which has means for the rapid exchange of the catheter over a guidewire without the utilization of an exchange wire or an extension wire, comprising:

a) an elongated catheter shaft having proximal and distal ends and being configured for percutaneous introduction into the patient's femoral artery;

b) a distal guidewire opening in the distal end of the catheter shaft;

c) a proximal guidewire opening in the catheter shaft spaced a short distance proximally from the distal guidewire opening and a substantial distance from the proximal end of the catheter shaft;

d) a flexible distal shaft section configured to be advanceable within the patient's coronary arteries having

a first inner lumen which extends proximally from the distal guidewire opening to the proximal guidewire opening and which is configured to slidably receive a guidewire therein,

a second inner lumen which is coextensive at least in part with the guidewire-receiving first inner lumen and which is configured to direct inflation fluid therethrough,

a third inner lumen which is coextensive with the first inner lumen and which is configured to be in fluid communication with a second opening in the distal end of the catheter shaft, and

an inflatable dilatation balloon on the distal shaft section having an interior which is in fluid communication with the second inner lumen and being spaced closer to the distal end of the shaft than the proximal guidewire port; and

e) a proximal shaft section much longer than the distal shaft section which is a single elongated tubular member with two inner lumens extending therein, one of the two inner lumens being in fluid communication with the second inner lumen in the distal shaft section and the other inner lumen being in fluid communication with the third inner lumen in the distal shaft section.

* * * * *

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Patent Bibliographic Data					07/02/2008 02:39 PM
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Issue Date:	09/19/1995		Filing Date:	03/09/1994	
Title:	ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES AND METHOD				
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Fee Code:					
Surcharge Fee Code:					
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of	)	Examiner M. Thaler
Paul G. Yock	)	Group Art Unit 3309
For: **ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES AND METHOD**	)	
Serial No.: 08/208,972	)	
Filed: March 9, 1994	)	
Matter No.: 18000.0029.0	)	

November 28, 1994

TERMINAL DISCLAIMER

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The Commissioner
United States Patent
and Trademark Office
Washington, DC 20231

Dear Sir:

I, Paul G. Yock, am the sole inventor and am owner of all right, title and interest in and to the above-identified application and U.S. Patent No. 5,061,273. While I have granted certain licenses to third parties with respect to the above application and patent, I still retain all ownership therein and as a result there are no documents to review with respect to ownership. I hereby certify that the title to the above-identified application remains with me.

P 30322 03/13/95 08208972 03-38211 030 148 110.00CH

I hereby disclaim the terminal portion of any patent which is granted on the above-identified application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 5,061,273.

It is hereby agreed that any patent granted on the above-identified application shall be enforceable only for and during such period that the legal title to any patent granted on the above-identified application shall be the same as the legal title to U.S. Patent 5,061,273. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the grantor, its successors or assigns.

No disclaimer is hereby made on any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term of U.S. Patent 5,061,273 in the event that it later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321 (a), has all claims cancelled by a reexamination certificate, or is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Dated: 12/2/94

Paul G. Yock

Exhibit E

APPENDIX 3-A

XIENCE V IFU

Note: The attached appendix is independently paginated

The XIENCE™ V Everolimus Eluting Coronary Stent System
Instructions for Use

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Table of Contents

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1.0 PRODUCT DESCRIPTION

The XIENCE™ V Everolimus Eluting Coronary Stent System (XIENCE V EECSS or XIENCE V stent system) is a device/drug combination product consisting of either the MULTI-LINK VISION® Coronary Stent System or the MULTI-LINK MINI VISION® Coronary Stent System coated with a formulation containing everolimus, the active ingredient, embedded in a non-erodible polymer.

1.1 Device Component Description

The device component consists of the MULTI-LINK MINI VISION or MULTI-LINK VISION stent mounted onto the MULTI-LINK MINI VISION or MULTI-LINK VISION stent delivery system (SDS) respectively. The device component characteristics are summarized in Table 1-1.

Table 1-1: XIENCE V Stent System Product Description

<table>
<tr><th></th><th>XIENCE V Rapid-Exchange (RX) EECSS</th><th>XIENCE V Over-the-Wire (OTW) EECSS</th></tr>
<tr><td>Available Stent Lengths (mm)</td><td colspan="2">8, 12, 15, 18, 23, 28</td></tr>
<tr><td>Available Stent Diameters (mm)</td><td colspan="2">2.5, 2.75, 3.0, 3.5, 4.0</td></tr>
<tr><td>Stent Material</td><td colspan="2">A medical grade L-605 cobalt chromium (CoCr) alloy MULTI-LINK VISION or MULTI-LINK MINI VISION stent</td></tr>
<tr><td>Drug Component</td><td colspan="2">A conformal coating of a non-erodible polymer loaded with 100 µg/cm^2 of everolimus with a maximum nominal drug content of 181 µg on the large stent (4.0 x 28 mm)</td></tr>
<tr><td>Delivery System Working Length</td><td>143 cm</td><td>143 cm</td></tr>
<tr><td>Delivery System Design</td><td>Single access port to inflation lumen. Guide wire exit notch is located 30 cm from tip. Designed for guide wires ≤ 0.014".</td><td>Sidearm adaptor provides access to balloon inflation/deflation lumen and guide wire lumen. Designed for guide wires ≤ 0.014".</td></tr>
<tr><td>Stent Delivery System Balloon</td><td colspan="2">A compliant, tapered balloon, with two radiopaque markers located on the catheter shaft to indicate balloon positioning and expanded stent length.</td></tr>
<tr><td>Balloon Inflation Pressure</td><td colspan="2">Nominal inflation pressure:
8 atm (811 kPa) for 2.5 and 2.75 mm diameters;
9 atm (912 kPa) for 3.0, 3.5, and 4.0 mm diameters
Rated Burst Pressure (RBP): 16 atm (1621 kPa) for all sizes</td></tr>
<tr><td>Guiding Catheter Inner Diameter</td><td colspan="2">≥ 5 F (0.056")</td></tr>
<tr><td>Catheter Shaft Outer Diameter (nominal)</td><td><u>2.5–3.0 mm</u> / <u>3.5–4.0 mm</u>
Distal: 0.032" / 0.035"
Proximal: 0.026" / 0.026"</td><td><u>2.5 mm</u> / <u>2.75 x 8 – 3.5 x 18</u> / <u>3.5 x 23 – 4.0 x 28</u>
Distal: 0.032" / 0.034" / 0.036"
Proximal: 0.042" / 0.042" / 0.042"</td></tr>
</table>

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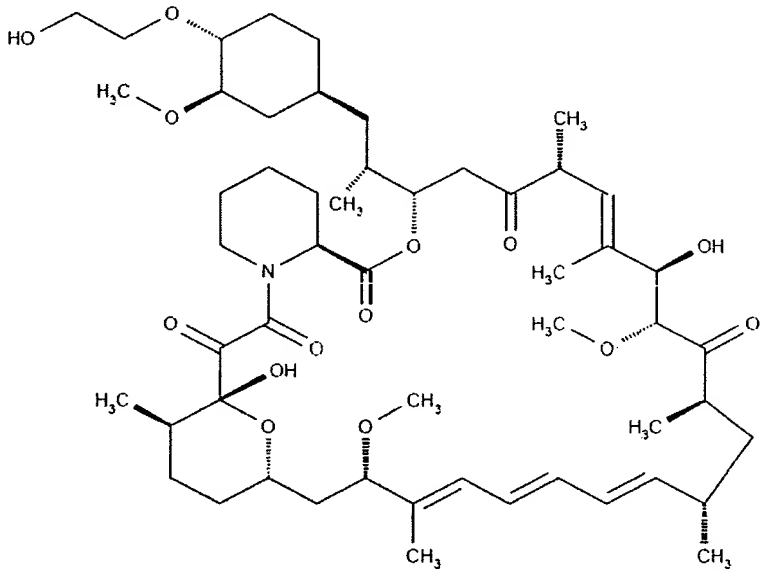
1.2 Drug Component Description

The XIENCE V Everolimus Eluting Coronary Stent (XIENCE V stent) is coated with everolimus (active ingredient), embedded in a non-erodible polymer (inactive ingredient).

1.2.1 Everolimus

Everolimus is the active pharmaceutical ingredient in the XIENCE V stent. It is a novel semi-synthetic macrolide immunosuppressant, synthesized by chemical modification of rapamycin (sirolimus). The everolimus chemical name is 40-O-(2-hydroxyethyl)-rapamycin and the chemical structure is shown in Figure 1-1 below.

Figure 1-1: Everolimus Chemical Structure



1.2.2. Inactive Ingredients – Non-erodible Polymer

The XIENCE V stent contains inactive ingredients including poly n-butyl methacrylate (PBMA), a polymer that adheres to the stent and drug coating, and PVDF-HFP, which is comprised of vinylidene fluoride and hexafluoropropylene monomers as the drug matrix layer containing everolimus. PBMA is a homopolymer with a molecular weight (Mw) of 264,000 to 376,000 dalton. PVDF-HFP is a non-erodible semi-crystalline random copolymer with a molecular weight (Mw) of 254,000 to 293,000 dalton. The drug matrix copolymer is mixed with everolimus (83%/17% w/w polymer/everolimus ratio) and applied to the entire PBMA coated stent surface. The drug load is 100 $\mu g/cm^2$ for all product sizes. No topcoat layer is used. The polymer chemical structures are shown in Figure 1-2 below.

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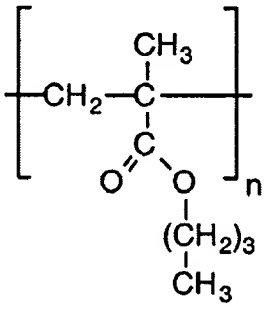
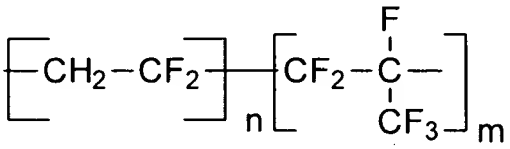
Figure 1-2: Non-erodible Polymer Chemical Structures

PBMA	PVDF-HFP
	

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1.2.3 Product Matrix and Everolimus Content

Table 1-3: XIENCE V EECSS Product Matrix and Everolimus Content

Model Number (RX)	Model Number (OTW)	Nominal Expanded Stent Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Everolimus Content (μg)
1009539-08	1009545-08	2.5	8	37
1009540-08	1009546-08	2.75	8	37
1009541-08	1009547-08	3.0	8	37
1009542-08	1009548-08	3.5	8	53
1009543-08	1009549-08	4.0	8	53
1009539-12	1009545-12	2.5	12	56
1009540-12	1009546-12	2.75	12	56
1009541-12	1009547-12	3.0	12	56
1009542-12	1009548-12	3.5	12	75
1009543-12	1009549-12	4.0	12	75
1009539-15	1009545-15	2.5	15	75
1009540-15	1009546-15	2.75	15	75
1009541-15	1009547-15	3.0	15	75
1009542-15	1009548-15	3.5	15	98
1009543-15	1009549-15	4.0	15	98
1009539-18	1009545-18	2.5	18	88
1009540-18	1009546-18	2.75	18	88
1009541-18	1009547-18	3.0	18	88
1009542-18	1009548-18	3.5	18	113
1009543-18	1009549-18	4.0	18	113
1009539-23	1009545-23	2.5	23	113
1009540-23	1009546-23	2.75	23	113
1009541-23	1009547-23	3.0	23	113
1009542-23	1009548-23	3.5	23	151
1009543-23	1009549-23	4.0	23	151
1009539-28	1009545-28	2.5	28	132
1009540-28	1009546-28	2.75	28	132
1009541-28	1009547-28	3.0	28	132
1009542-28	1009548-28	3.5	28	181
1009543-28	1009549-28	4.0	28	181

2.0 INDICATIONS

The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

3.0 CONTRAINDICATIONS

The XIENCE V stent is contraindicated for use in patients:

- Who cannot receive antiplatelet and/or anti-coagulant therapy (see **Section 5.2 Pre- and Post-Procedure Antiplatelet Regimen** for more information)
- With lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- With hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers

4.0 WARNINGS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Judicious patient selection is necessary because device use has been associated with stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy (see Section 5.2 for important information regarding antiplatelet therapy).

5.0 PRECAUTIONS

5.1 General Precautions

- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent is presently unknown.
- Risks and benefits should be considered in patients with severe contrast agent allergies.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment, and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death. Data from the XIENCE V SPIRIT family of trials have been prospectively evaluated and adjudicated using both the protocol definition of stent thrombosis and the definition developed by the Academic

PAGES 8-52 INTENTIONALLY OMITTED

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

11.0 PATIENT COUNSELING AND PATIENT INFORMATION

Physicians should consider the following in counseling patients about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with an everolimus-eluting stent.
- Discuss the risks of early discontinuation of the antiplatelet therapy.
- Discuss the risks of late stent thrombosis with DES use in higher risk patient subgroups.
- Discuss the risk/benefit issues for this particular patient.
- Discuss alteration to current life-style immediately following the procedure and over the long term.

The following patient materials are available for this product:

- A Patient Information Guide which includes information on coronary artery disease, the implant procedure and the XIENCE V Everolimus Eluting Coronary Stent System (provided to physician, on-line at www.XIENCEV.com/PatientGuide, or by calling customer service 1-800-227-9902).
- A Stent Implant Card that includes both patient information and stent implant information (provided in package)

12.0 HOW SUPPLIED

Sterile: This device is sterilized with ethylene oxide gas, non-pyrogenic. It is intended for single use only. Do not resterilize. Do not use if the package is opened or damaged.

Contents: One (1) XIENCE V Everolimus Eluting Coronary Stent System, one (1) Flushing tool, (for the XIENCE V EECSS Rapid Exchange (RX) Stent System), one (1) Stent Implant Card, one (1) Patient Information Guide.

Storage: Store in a dry, dark, cool place. Protect from light. Do not remove from carton until ready for use. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

13.0 OPERATOR'S INSTRUCTIONS

13.1 Inspection Prior to Use

- Carefully inspect the sterile package before opening and check for damage to the sterile barrier. Do not use if the integrity of the sterile package has been compromised.
- Do not use after the "Use By" date.
- Tear open the foil pouch and remove the inner pouch. **Note: the outside of the inner pouch is NOT sterile.** Open the inner pouch and pass or drop the product into the sterile field using an aseptic technique.
- Prior to using the XIENCE V Everolimus Eluting Coronary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent does not extend beyond the radiopaque balloon markers. Do not

use if any defects are noted. However, **do not manipulate, touch, or handle the stent** with your fingers, which may cause coating damage, contamination or stent dislodgement from the delivery balloon.

Note: At any time during use of the XIENCE V Rapid Exchange (RX) EECSS, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

13.2 Materials Required

- Appropriate guiding catheter(s). See Table 1-1, XIENCE V Stent System Product Description
- 2 – 3 syringes (10 – 20 ml)
- 1,000 u/500 ml Heparinized Normal Saline (HepNS)
- 0.014 inch (0.36 mm) x 175 cm (minimum length) guide wire
- Rotating hemostatic valve with appropriate minimum inner diameter [0.096 inch (2.44 mm)]
- 60% contrast diluted 1:1 with heparinized normal saline
- Inflation device
- Pre-deployment dilatation catheter
- Three-way stopcock
- Torque device
- Guide wire introducer
- Appropriate arterial sheath
- Appropriate anticoagulation and antiplatelet drugs

13.3 Preparation

13.3.1 Packaging Removal

Note: The foil pouch is not a sterile barrier. The inner header bag (pouch) within the foil pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

1. Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using a Rapid Exchange (RX) system, do not bend or kink the hypotube during removal.

2. Remove the product mandrel and protective stent sheath by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector and gently remove distally. If unusual resistance is felt during product mandrel and stent sheath removal, do not use this product and replace with another. Follow product returns procedure for the unused device.

13.3.2 Guide Wire Lumen Flush

1. Over the Wire (OTW) only: Flush the guide wire lumen with HepNS until fluid exits the distal end of the delivery system.

2. Rapid Exchange (RX) only: Flush the guide wire lumen with HepNS using the flushing tool supplied with the product. Insert the flushing tool into the tip of the catheter and flush until fluid exits the guide wire exit notch.

Note: Avoid manipulation of the stent while flushing the guide wire lumen, as this may disrupt the placement of the stent on the balloon.

13.3.3 Delivery System Preparation

1. Prepare an inflation device/syringe with diluted contrast medium.

2. Attach an inflation device/syringe to the stopcock; attach it to the inflation port of the product. Do not bend the product hypotube when connecting to the inflation device/syringe.

3. With the tip down, orient the delivery system vertically.

4. Open the stopcock to delivery system; pull negative for 30 seconds; release to neutral for contrast fill.

5. Close the stopcock to the delivery system; purge the inflation device/syringe of all air.

6. Repeat steps 3 through 5 until all air is expelled. If bubbles persist, do not use the product.

7. If a syringe was used, attach a prepared inflation device to stopcock.

8. Open the stopcock to the delivery system.

9. Leave on neutral

Note: If air is seen in the shaft, repeat *Delivery System Preparation* steps 3 through 5 to prevent uneven stent expansion.

13.4 Delivery Procedure

1. Prepare the vascular access site according to standard practice.

2. **Pre-dilate the lesion with a PTCA catheter of appropriate length and diameter for the vessel/lesion to be treated.** Limit the longitudinal length of pre-dilatation by the PTCA balloon to avoid creating a region of vessel injury that is outside the boundaries of the XIENCE V Stent.

Note: The labeled stent diameter refers to expanded stent inner diameter.

3. Maintain neutral pressure on the inflation device attached to the delivery system. Open the rotating hemostatic valve as wide as possible.

4. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.

5. Carefully advance the delivery system into the guiding catheter and over the guide wire to the target lesion. When using a Rapid Exchange (RX) system be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the stent system into the coronary artery.

Note: If unusual resistance is felt before the stent exits the guiding catheter, do not force passage. Resistance may indicate a problem and the use of excessive force may result in stent damage or disiodgement. Maintain guide wire placement across the lesion and remove the delivery system and guiding catheter as a single unit.

6. Advance the delivery system over the guide wire to the target lesion under direct fluoroscopic visualization. Utilize the radiopaque balloon markers to position the stent across the lesion. Perform angiography to confirm stent position. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Section 5.14 – Precautions, Delivery System Removal). The balloon markers indicate both the stent edges and the balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, **remove the entire system as a single unit.** See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

7. Tighten the rotating hemostatic valve. The stent is now ready to be deployed.

13.5 Deployment Procedure

CAUTION: Refer to Table 14-1: Typical XIENCE V Stent Compliance for *in vitro* stent inner diameter, nominal pressure, and RBP.

1. Prior to deployment, reconfirm the correct position of the stent relative to the target lesion using the radiopaque balloon markers.

2. Deploy the stent slowly by pressurizing the delivery system in 2 atm increments, every 5 seconds, until stent is completely expanded. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter ratio of about 1.1 times the reference vessel diameter (see Table 14-1). Maintain pressure for 30 seconds. If necessary, the delivery system can be repressurized or further pressurized to assure complete apposition of the stent to the artery wall. **Do not exceed the labeled rated burst pressure (RBP) of 16 atm (1.62 MPa).**

3. Fully cover the entire lesion and balloon treated area (including dissections) with the XIENCE V stent, allowing for adequate stent coverage into healthy tissue proximal and distal to the lesion.

4. Deflate the balloon by pulling negative on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to guiding catheter position.

5. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. Stent wall contact should be verified through routine angiography or intravascular ultrasound (IVUS).

6. If the deployed stent size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent. If the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high pressure, non-compliant balloon dilatation catheter. If this is required, the stented segment should be carefully recrossed with a prolapsed guide wire to avoid disrupting the stent geometry. Deployed stents should not be left under-dilated.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

7. If more than one XIENCE V stent is needed to cover the lesion and balloon

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treated area, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped. To ensure that there are no gaps between stents the balloon marker bands of the second XIENCE V stent should be positioned inside the deployed stent prior to expansion.

8. Reconfirm stent position and angiographic results. Repeat inflations until optimal stent deployment is achieved.

13.6 Removal Procedure

1. Deflate the balloon by pulling negative pressure on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to the guiding catheter position.

2. Fully open the rotating hemostatic valve.

3. While maintaining the guide wire position and negative pressure on the inflation device, withdraw the delivery system.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, the entire system should be **removed as a single unit.** See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

4. Tighten the rotating hemostatic valve.

5. Repeat angiography to assess the stented area. If post-dilatation is necessary, ensure that the final stent diameter matches the reference vessel diameter. **Assure that the stent is not under-dilated.**

13.7 Post-Deployment Dilatation of Stent Segments

1. All efforts should be taken to assure that the stent is not underdilated. If the deployed stent size is still inadequate with respect to the vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further. The stent may be further expanded using a low profile, high pressure, and non-compliant balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guide wire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

14.0 *IN VITRO* COMPLIANCE INFORMATION

Table 14-1: Typical XIENCE V Stent Compliance
Nominal pressure for each diameter indicated by bold font.

Pressure		Stent ID (mm) by System Size				
(atm)	(MPa)	2.5 mm	2.75 mm	3.0 mm	3.5 mm	4.0 mm
8	0.81	**2.46**	**2.74**	2.90	3.46	3.86
9	0.91	2.52	2.81	**2.97**	**3.55**	**3.95**
10	1.01	2.58	2.87	3.04	3.63	4.03
11	1.11	2.63	2.92	3.10	3.69	4.10
12	1.22	2.68	2.97	3.15	3.75	4.17
13	1.32	2.72	3.01	3.19	3.80	4.23
14	1.42	2.75	3.05	3.23	3.84	4.28
15	1.52	2.78	3.08	3.26	3.89	4.33
16 (RBP)*	1.62	2.81	3.11	3.30	3.93	4.37
17	1.72	2.84	3.14	3.33	3.97	4.42
18	1.82	2.87	3.18	3.36	4.00	4.46

Note: These nominal data are based on *in vitro* testing at 37°C and do not take into account lesion resistance. Ensure full deployment of the stent (see Section 13.5, Operator's Instructions, Deployment Procedure) and confirm the stent sizing angiographically.
*Do not exceed the rated burst pressure (RBP).

15.0 REUSE PRECAUTION STATEMENT

Do not use if sterile barrier is damaged. If damage is found call your Abbott Vascular, Cardiac Therapies representative.

For single patient use only. Do not reuse, reprocess or resterilize.

16.0 PATENTS

This product and/or its use are covered by one or more of the following United States patents: 5,040,548 ; 5,061,273 ; 5,154,725 ; 5,234,002 ; 5,242,396 ; 5,350,395 ; 5,451,233 ; 5,496,346 ; 5,514,154 ; 5,569,295 ; 5,603,721 ; 5,636,641 ; 5,649,952 ; 5,728,158 ; 5,735,893 ; 5,759,192 ; 5,780,807 ; 5,868,706 ; 6,056,776 ; 6,131,266 ; 6,179,810 ; 6,273,911 ; 6,309,412 ; 6,312,459 ; 6,369,355 ; 6,419,693 ; 6,432,133 ; 6,482,166 ; 6,485,511 ; 6,629,991 ; 6,629,994 ; 6,651,478 ; 6,656,220 ; 6,736,843 ; 6,746,423 ; 6,753,071 ; 6,818,247 ; 6,827,734 ; 6,887,219 ; 6,887,510 ; 6,890,318 ; 6,908,479 ; 6,921,411 ; 6,929,657 ; 6,939,373 ; 6,957,152. Other US patents pending. Foreign patents issued and pending.

XIENCE V, MULTI-LINK VISION, and MULTI-LINK MINI VISION are trademarks of the Abbott Group of Companies.

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Graphical Symbols for Medical Device Labeling

 Manufacturer	REF Catalogue Number	F French Size
 Do not reuse, do not resterilize	STERILE EO Sterilized using Ethylene Oxide	 Consult Instructions for Use
 Use By	LOT Batch Code	 Date of Manufacture
 Guiding Catheter	PYROGEN Non-Pyrogenic	 Contents (Numeral represents quantity of units inside)
 Inner Diameter		

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XIENCE™ V Everolimus Eluting Coronary Stent System Regulatory Summary

Description	FDA Contact	Dated	Originator
Original Pre-IDE for XIENCE V EECSS & SPRIT III clinical trial	IDE Document Mail Center	2/11/05	ABT
Original IDE for XIENCE V EECSS and SPIRIT III clinical trial	IDE Document Mail Center	3/6/05	ABT
FDA disapproval of IDE	Bram Zuckerman	4/6/05	FDA
FDA Meeting: Animal and Biocompatibility Compliance	Heather Agler	4/12/05	
Response to FDA letter dated April 6, 2005	IDE Document Mail Center	4/15/05	ABT
Additional ABT response to FDA letter dated April 6, 2005	IDE Document Mail Center	4/29/05	ABT
FDA conditional IDE approval	Bram Zuckerman	5/4/05	FDA
Response to FDA letter dated May 4, 2005	IDE Document Mail Center	5/6/05	ABT
Additional ABT response to FDA letter dated May 4, 2005	IDE Document Mail Center	5/13/05	ABT
FDA Meeting: Short Term Biocompatibility	Heather Agler	5/16/05	
Response to FDA teleconference May 16, 2005	IDE Document Mail Center	5/25/05	ABT
FDA questions for A004 and S001	Bram Zuckerman	5/27/05	FDA
FDA questions for A004 and S001	Bram Zuckerman	5/27/05	FDA
FDA questions for S002	Bram Zuckerman	6/15/05	FDA
Additional ABT response to FDA letter dated May 4, 2005	IDE Document Mail Center	6/17/05	ABT
FDA questions for S003	Bram Zuckerman	6/24/05	FDA
FDA Meeting: Cytotoxicity and Hemolysis	Heather Agler	7/15/05	
FDA questions for S004	Bram Zuckerman	7/20/05	FDA
Response to FDA letter dated Jun 15 and Jun 24, 2005	IDE Document Mail Center	7/29/05	ABT
FDA Meeting: Intracutaneous Reactivity and Sensitization	Heather Agler	8/11/05	
FDA questions for S005	Bram Zuckerman	8/18/05	FDA
Response to FDA letter dated July 20, 2005	IDE Document Mail Center	9/16/05	ABT
FDA questions for S007	Bram Zuckerman	10/14/05	FDA
FDA response to S008	Bram Zuckerman	10/14/05	FDA
FDA Meeting: Spirit IV Trial Design	Heather Agler	11/3/05	
6-month progress report	IDE Document Mail Center	11/4/05	ABT
Response to FDA letter dated Oct 14, 2005	IDE Document Mail Center	11/23/05	ABT
FDA questions for S009	Bram Zuckerman	12/7/05	FDA
FDA questions for S010	Bram Zuckerman	12/21/05	FDA
Shelf life extension submission	IDE Document Mail Center	1/19/06	ABT
Response to FDA letters dated Dec 7 and Dec 21, 2005	IDE Document Mail Center	2/3/06	ABT
SPIRIT IV clinical trial submission	IDE Document Mail Center	2/10/06	ABT
FDA questions for S014	Bram Zuckerman	2/17/06	FDA
FDA Meeting: Adaptive Clinical trial design	Heather Agler	3/8/06	
FDA questions for S015	Bram Zuckerman	3/8/06	FDA
FDA questions for S016	Bram Zuckerman	3/15/06	FDA
Notification of a sponsor-initiated investigational device return	IDE Document Mail Center	3/18/06	ABT
Response to FDA letters dated Feb 17 and Mar 8, 2006	IDE Document Mail Center	4/21/06	ABT
FDA Meeting: Carcinogenicity	Heather Agler	4/24/06	
FDA Meeting: Drug Release	Heather Agler	4/27/06	
Response to FDA letters dated Mar 15, 2006	IDE Document Mail Center	4/28/06	ABT
Annual progress report	IDE Document Mail Center	5/4/06	ABT

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Description	FDA Contact	Dated	Originator
FDA questions for S021	Bram Zuckerman	5/25/06	FDA
FDA questions for S022	Bram Zuckerman	5/31/06	FDA
Request for resumption of SPIRIT III clinical trial	IDE Document Mail Center	6/22/06	ABT
PMA Module 1 - pre-cinical, non-clinical	PMA Document Mail Center	7/14/06	ABT
FDA response for S025 (approval)	Bram Zuckerman	7/21/06	FDA
Responses to FDA letters dated May 24, May 312006 and other FDA committments	IDE Document Mail Center	7/26/06	ABT
FDA questions for S029	Bram Zuckerman	8/25/06	FDA
FDA Meeting: Stent Design	Heather Agler	10/6/06	
6-month progress report	IDE Document Mail Center	11/4/06	ABT
Response to FDA letter dated Aug 30, 2006	IDE Document Mail Center	11/15/06	ABT
FDA questions for S033	Bram Zuckerman	11/15/06	FDA
Notification of manufacturing / sterilization change and response to FDA letter dated Nov 16, 2006	IDE Document Mail Center	12/28/06	ABT
FDA questions for S040	Bram Zuckerman	12/29/06	FDA
FDA questions for S043	Bram Zuckerman	1/19/07	FDA
Response to FDA letter dated Dec 29, 2006	IDE Document Mail Center	1/26/07	ABT
FDA questions for S044	Bram Zuckerman	2/2/07	FDA
FDA questions for S045	Bram Zuckerman	2/28/07	FDA
Response to FDA letter dated Feb 2, 2007	IDE Document Mail Center	3/1/07	ABT
Request for SPIRIT IV expansion	IDE Document Mail Center	3/9/07	ABT
PMA Module 2 - manufacturing information, bench testing, clinical	PMA Document Mail Center	3/23/07	ABT
FDA questions for S048	Bram Zuckerman	3/30/07	FDA
Response to FDA letter dated Feb 28, 2007	IDE Document Mail Center	4/11/07	ABT
Annual progress report	IDE Document Mail Center	5/3/07	ABT
Response to FDA letter dated Mar 30, 2007	IDE Document Mail Center	5/11/07	ABT
FDA approval for S053	Bram Zuckerman	5/11/07	FDA
FDA questions for S050	Bram Zuckerman	5/23/07	FDA
PMA Module 3 - clinical and labeling	PMA Document Mail Center	5/31/07	ABT
FDA deficiencies reponse for PMA		6/13/07	FDA
FDA questions for S056	Bram Zuckerman	6/27/07	FDA
Response to FDA letter from Office of Compliance letter dated Jun 13, 2007	PMA Document Mail Center	7/3/07	ABT
FDA questions for S062	Bram Zuckerman	7/18/07	FDA
FDA Meeting: IDE and PMA Submission Timing	Heather Agler	7/24/07	
FDA Office of Compliance quality system questions	Heather Agler	8/3/07	FDA
Response to FDA letter from Office of Compliance letter dated Aug 3, 2007	PMA Document Mail Center	8/31/07	ABT
Office of Device Evaluation questions to PMA		9/7/07	FDA
FDA Meeting: 100 Day Meeting	Heather Agler	9/12/07	
FDA Meeting: PMA Bench Testing	Heather Agler	9/20/07	
XIENCE V USA clinical trial submission	IDE Document Mail Center	9/21/07	ABT
FDA questions for S068	Bram Zuckerman	10/5/07	FDA
FDA Meeting: SPIRIT Trial 2 year data for Panel	Heather Agler	10/17/07	

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Description	FDA Contact	Dated	Originator
Draft panel pack provided to FDA		10/19/07	ABT
FDA questions for S069	Bram Zuckerman	10/23/07	FDA
FDA comments regarding panel pack		10/26/07	FDA
Final panel pack provided to FDA		10/29/07	ABT
FDA issues executive summary		10/31/07	FDA
Submission of comments on FDA executive summary		11/2/07	ABT
Submission of amendment to panel pack		11/5/07	ABT
Response to FDA letter dated Sep 7, 2007	PMA Document Mail Center	11/7/07	ABT
Response to FDA letter dated Sep 7, 2007	PMA Document Mail Center	12/11/07	ABT
Request for single compassionate use treatment	IDE Document Mail Center	12/21/07	ABT
Advisory Panel Meeting	Heather Agler	11/29/07	
SPIRIT III statistical analysis plan update	IDE Document Mail Center	12/29/07	ABT
Pre-Approval Inspection response		1/18/08	FDA
FDA Meeting: MRI	Heather Agler	1/24/08	
FDA Meeting: XIENCE V USA Clinical Trial	Heather Agler	1/30/08	
Pre-Approval Inspection response		2/8/08	FDA
Pre-Approval Inspection response		2/8/08	FDA
Meeting: SPIRIT IV logistics	Heather Agler	2/14/08	
SPIRIT II/III 1 and 2-year meta-analysis	PMA Document Mail Center	2/19/08	ABT
FDA Meeting: PMA Particulate Test Method	Heather Agler	2/25/08	
FDA Meeting: MRI	Heather Agler	3/10/08	
Response to FDA letter Sep 7, 2007 - Non-clinical bench technical documents	PMA Document Mail Center	4/1/08	ABT
FDA response for S088	Bram Zuckerman	4/4/08	FDA
FDA Meeting: PMA Particulate Test Method	Heather Agler	4/4/08	
XIENCE V USA clinical trial update	IDE Document Mail Center	4/28/08	ABT
FDA questions for S097		4/29/08	FDA
FDA Meeting: MRI and SPIRIT III 2 year data update	Heather Agler	5/1/08	
FDA Meeting: PMA CDER Analytical Test Methods	Heather Agler	5/8/08	
Response to FDA letter Sep 7, 2007 - MRI statements	PMA Document Mail Center	5/8/08	ABT
FDA Meeting: PMA CDER Analytical Test Methods	Heather Agler	5/8/08	
FDA Meeting: MRI	Heather Agler	5/9/08	
Response to FDA letter Sep 7, 2007	PMA Document Mail Center	5/12/08	ABT
FDA response to S094		5/16/08	FDA
FDA response for S099		5/29/08	FDA
FDA Meeting: PMA Polymer Material Control	Heather Agler	6/5/08	
Response to FDA letter Sep 7, 2007	PMA Document Mail Center	6/6/08	ABT
ODE Responses	PMA Document Mail Center	6/21/08	ABT
ODE Responses	PMA Document Mail Center	6/25/08	ABT

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Description	FDA Contact	Dated	Originator
Final Labeling	PMA Document Mail Center	7/2/08	ABT
Annual Report	PMA Document Mail Center	7/2/08	ABT
FDA approval of PMA P070015	Donna Bea-Tillman, Ph.D.	7/2/08	FDA